

## **Exhibit A**



*United States Department of Justice*

*United States Attorney  
Southern District of West Virginia*

*Robert C. Byrd United States Courthouse  
300 Virginia Street, East  
Suite 4000  
Charleston, WV 25301  
1-800-659-8726*

*Mailing Address  
Post Office Box 1713  
Charleston, WV 25326  
304-345-2200  
FAX: 304-347-5443*

April 24, 2020

**VIA E-MAIL**

Laura Flahive Wu  
Covington & Burling LLC  
One City Center  
850 Tenth Street, N.W.  
Washington, D.C. 20001-4956

Re: Touhy Request in City of Huntington v. AmerisourceBergen Drug Corp., et al., 3:17-01362, and Cabell County Commission v. AmerisourceBergen Drug Corp., et al., 3:17-01665 (S.D.W.Va.)

Dear Ms. Wu:

The United States Department of Justice ("DOJ") received the attached February 21, 2020 letter in which you request disclosure of official DOJ information. *See Exhibit 1.* Specifically, you ask the United States Drug Enforcement Administration ("DEA") to provide documents detailing 24 years of DEA operations in response to 36 individual document requests; and testimony on 30 different topics under Rule 30(b)(6) of the Federal Rules of Civil Procedure.<sup>1</sup>

As you are aware, federal regulations govern the disclosure of official DOJ information by federal employees and agencies, including the DEA. 28 C.F.R. § 16.21-.29. These regulations apply where, as here, the United States is not a party to the proceeding. Under those regulations, current and former DEA employees are prohibited from disclosing official information absent express authorization from DOJ. 28 C.F.R. § 16.22(a). The Supreme held that a federal employee could not be held in contempt for refusing to produce subpoenaed

<sup>1</sup> The text of your February 21, 2020 letter (at pp. 2-4) includes an unnumbered, bullet-pointed list of approximately 30 topics for both documents and testimony. This list overlaps, but does not correspond directly, with the 36 numbered document requests in the attached version of Defendants' document subpoena to the DEA (Exhibit 1 to the February 21, 2020 Letter) and the 17 numbered topics for 30(b)(6) examination in the attached version of Defendants' testimony subpoena to the DEA (Exhibit 2 to the February 21, 2020 Letter). Some of the 36 document requests and/or 17 topics for testimony appear to have been omitted from the list in your February 21, 2020 letter. On March 11, 2020, Defendants provided to the United States updated subpoenas for documents and testimony. The March 11, 2020 document subpoena ("Defendants' Subpoena for Documents," attached as **Exhibit 2**) contains 36 document requests. The March 11, 2020 subpoena for testimony ("Defendants' Subpoena for Testimony," attached as **Exhibit 3**) contains 30 topics for 30(b)(6) examination. For purposes of this response, I assume you intended for your letter to request the information described in the numbered document requests in Defendants' Subpoenas for Documents and Testimony to the DEA. For clarity all pin-cites in this letter refer to the numbered requests in Defendants' Subpoenas for Documents and Testimony to the DEA.

Laura Flahive Wu  
April 24, 2020  
Page 2

documents, where his refusal was based on regulations prohibiting the disclosure of official information without prior authorization. 340 U.S. 462, 468 (1951). Nor did such regulations invade the courts' authority to determine the admissibility of evidence. *Id.* at 468-70. This authority emanates from the federal government's sovereign immunity, even when a subpoena is directed against a federal agency or a federal employee or involves a subpoena for documents. *See COMSAT Corp. v. Nat'l Science Found.*, 190 F.3d 269, 277 (4th Cir. 1999).

Your compliance with the *Touhy* regulations is a condition precedent to obtaining testimony or other information from a current or former DOJ employee. *See Smith v. Cromer*, 159 F.3d 875, 879-80 (4th Cir. 1998); *United States v. Wallace*, 32 F.3d 921 (5th Cir. 1994); *United States v. Bizzard*, 674 F.2d 1382 (11th Cir. 1982). The government has a "legitimate interest in orderly governmental operations and the proper use of officials' time." *Alex v. Jasper Wyman & Son*, 115 F.R.D. 156, 157 (D. Me. 1986). These concerns are especially significant when live testimony is requested from a federal agency. In the face of such a request, "an agency's choice of whether or not to comply with a third-party subpoena is essentially a policy decision about the best use of the agency's resources." *Puerto Rico v. United States*, 490 F.3d 50, 61 (1st Cir. 2007). Once an agency determines not to provide testimony "in the context of private litigation when the government is not a party, a court should not order testimony to be given . . . without the showing of a compelling interest." *Alex*, 115 F.R.D. at 157; *COMSAT*, 190 F.3d at 278 (to conserve agency resources and prevent a non-party agency from becoming embroiled in private litigation, the decision to permit employee testimony is committed to the agency's sole discretion). Whether the DEA and DOJ are required to produce documents or employees as witnesses in the context of these proceedings is a matter of the agency's discretion, sovereign immunity, and applicable federal law. *See COMSAT*, 190 F.3d at 278.

Pursuant to 28 C.F.R. § 16.22, I am the official responsible for consulting with the DEA and authorizing any disclosure in response to your request. Federal regulations require me to consider whether disclosure is appropriate under the applicable rules of procedure and law concerning privilege. 28 C.F.R. § 16.26(a). I also cannot release official information if disclosure would:

1. Violate a specific statute or regulation;
2. Reveal classified information;
3. Reveal a confidential source or informant;
4. Reveal investigative techniques or investigatory records compiled for law enforcement purposes; or
5. Reveal trade secrets without the owner's consent.

28 C.F.R. § 16.26(b).

After carefully considering your request, consulting with the DEA, applying all of the above factors, and reviewing the relevant procedural and substantive law, I have determined that



Laura Flahive Wu  
April 24, 2020  
Page 3

your requests are not appropriate under the procedural rules governing the case. Further, I find that releasing the requested information would not be appropriate under the law concerning privilege; nor would it be appropriate under 28 C.F.R. § 16.26(b).

1. **Your Document and Testimony Requests Are Unreasonably Cumulative and Duplicative.**

Your document and testimony requests are “unreasonably cumulative [and] duplicative” under Rule 26(b) of the Federal Rules of Civil Procedure, which sets forth the scope and limits of discovery in federal court. Courts limit the “frequency or extent of discovery” if they determine that “the discovery sought is unreasonably cumulative or duplicative.” Fed.R.Civ.P. 26(b)(2)(C).

Many of your requests are unreasonably cumulative or duplicative with discovery sought and obtained from the DEA in Track One-A of the MDL. When the MDL Court remanded this case to the Southern District of West Virginia, the court believed “only limited, jurisdiction-specific discovery in the West Virginia cases would be necessary after remand.” See **Exhibit 4**, Response to Motion for Clarification, Case No. 1:17-md-2804, Dkt. No. 351-1, at p. 2 (N.D. Ohio, April 17, 2020). Because of the extensive discovery taken from DEA in Track One-A, the MDL Court “did not believe that additional discovery from DEA was necessary or appropriate for a fair trial, applying the standards set out in Rules 26, 30, and 45 of the Federal Rules of Civil Procedure” following remand. See *id.* at p. 2-3. And yet, many of your requests for documents and testimony are not geographically limited to West Virginia and, as such, either were or should have been requested from the DEA in Track One-A. Those requests that do reference West Virginia in their text (such as your various requests for “DEA’s policies and procedures and trainings”) in fact seek documents that are nationwide in scope, or that would otherwise require DEA to revisit document repositories that the DEA already searched, or once again prepare deponents that DEA already made available to the parties in connection with Track One-A.

Discovery in MDL Track One-A imposed unique burdens on the DEA as a non-party, governmental agency. As acknowledged in the MDL Court’s Response to Motion for Clarification (**Exhibit 4**, at pp. 1-2), the DEA’s ultimate production in MDL Track One-A was the result of a time-consuming effort by the agency to narrow the initial universe of documents generated by the parties’ incredibly broad requests. First, the DEA collected roughly 65 million pages of documents from 11 custodians, some of whom had left the agency years prior. Second, DEA and DOJ engaged in extensive negotiations with the parties to identify a subset of custodians and search terms that would provide the parties with responsive documents. Third, because the majority of the documents captured by these searches contained privileged or law enforcement sensitive information, every document was meticulously reviewed to ensure its production would not reveal such information or otherwise jeopardize the DEA’s ability to carry out its critical mission. As part of this review, DEA conferred with other federal and state law

Laura Flahive Wu  
April 24, 2020  
Page 4

enforcement agencies to evaluate potentially privileged or protected information. And fifth, after making these document productions, the DEA authorized and prepared multiple current employees to provide 30(b)(6) testimony.

The DEA has limited resources to dedicate to responding to discovery as a non-party in civil litigation, and the above-described work in connection with MDL Track One-A relied significantly on the input and efforts of DEA personnel whose primary responsibilities are to prevent and investigate diversion. The requests in your February 21, 2020 letter would have the DEA undertake this entire process again. That is unreasonable. Moreover, it is inconsistent with the MDL Court's understanding that no further discovery from DEA would be needed in this case upon remand.

Additionally, many of your requests for 30(b)(6) testimony are unreasonably cumulative and duplicative with your document requests and with documents produced in Track One-A, insofar as they seek a DEA witness who would testify about information contained in documents.

For all of these reasons your requests are unreasonably cumulative and duplicative, and therefore contrary to Rule 26(b)(2)(C) of the Federal Rules of Civil Procedure.

**2. Your Request Fails to Provide a Summary of Information Sought.**

Your request fails to provide a summary of the testimony or information sought. A *Touhy* request must include "a statement by the party seeking the testimony or by his attorney, setting forth a summary of the testimony sought." 28 C.F.R. § 16.22(c); *see also* § 16.22(d). This statement is necessary to enable me to properly consider the propriety of the request and any applicable privileges or other prohibitions on disclosure. The statement also defines the scope of any authorized testimony. *Id.* § 16.22(c) ("Any authorization for testimony shall be limited to the scope of the demand as summarized in each statement."). I cannot properly make that assessment without the requisite summary from Defendants.

Instead, your letter (at p. 2) includes a broad and non-exhaustive list of topics on which you are seeking documents and that you wish to cover at depositions, as evidenced by your use of the phrase "relating, but not limited to" before your list of requested documents and topics for witness testimony. The 36 numbered document requests in Defendants' Subpoena for Documents and 30 numbered topics for 30(b)(6) testimony in Defendants' Subpoena for Testimony are, individually and collectively, just as broad. None of these requests is limited to a particular DEA case or category of DEA cases. Moreover, your request for 30(b)(6) testimony is not limited in time, and your request for documents purports to seek documents from 1996 to present. Your letter and Defendants' Subpoenas for Documents and Testimony simply do not provide a reasonably specific summary that would allow me to determine the propriety of your



Laura Flahive Wu  
April 24, 2020  
Page 5

requests, all privileges that may apply, or the scope of any authorized testimony or document productions.

**3. Your Request Fails to Provide a Statement of Relevance.**

Your request fails to detail why the information you seek is relevant to your defenses in the litigation. A *Touhy* request must include an explanation of the requested information's "relevance to the proceeding." 28 C.F.R. § 16.22(c); *see also* § 16.22(d).

While you assert that the official information "is crucial to Defendants' ability to defend against Plaintiffs' allegations regarding causation as well as assessing the reasonableness of Defendants' conduct," this conclusory statement does not explain how the requested information is specifically relevant to your defenses. For example, you have propounded multiple requests for documents or testimony concerning the DEA's use of, and communications concerning, Automation of Reports and Consolidated Orders System (ARCOS) and the Suspicious Order Reporting System (SORS). It is hard to see how information concerning the handling of ARCOS or SORS by the DEA, which is not a party to this litigation, is relevant to the claims or defenses in the underlying litigation between the parties. Indeed, your request fails even to articulate meaningfully the specific defenses you intend to develop through your numerous and expansive requests for documents and testimony to the DEA. Without this information, I am unable to evaluate the relevance of the requested information or to determine the scope of any disclosure that may be warranted here.

**4. Your Document and Testimony Requests Are Overly Broad and Unduly Burdensome.**

Your document and testimony requests are overly broad and unduly burdensome and therefore improper under Rules 26 and 45 of the Federal Rules of Civil Procedure. Courts routinely protect non-parties from the undue burden of discovery. *See, e.g., Cusumano v. Microsoft Corp.*, 162 F.3d 708, 717 (1st Cir. 1998) ("Although discovery is by definition invasive, parties to a lawsuit must accept its travails as a natural concomitant of modern civil litigation. Non-parties have a different set of expectations. Accordingly, concern for the unwanted burden thrust upon non-parties is a factor entitled to special weight in evaluating the balance of competing needs."); *Sahu v. Union Carbide Corp.*, 262 F.R.D. 308, 317 (S.D.N.Y. 2009) (stating that courts are more sensitive to discovery burdens on third parties).

Compliance with your requests for 30(b)(6) testimony on 30 topics and for DEA documents responsive to 36 individual document requests would be unduly burdensome to the DEA. It would take a disproportionate amount of time for DEA staff to locate, copy, review, and redact this exceptionally large volume of documents. In some instances, the requests effectively seek all documents of entire divisions or offices within the DEA. Aggravating this burden is the fact that you have propounded multiple requests seeking, or purporting to seek,

Laura Flahive Wu  
April 24, 2020  
Page 6

documents and testimony pertaining to open and closed DEA investigations. Production of such documents requires careful, resource-intensive review to redact privileged, law-enforcement sensitive, or otherwise protected information. Frequently, the DEA must also confer with other law enforcement agencies regarding any shared information. This burdensome review will disrupt the DEA's critical mission to prevent the diversion of controlled substances because Diversion Control Division staff with the relevant knowledge and expertise would be required to complete this task.

Your testimony requests are unduly burdensome for the additional reason that depositions are usually the most burdensome means of obtaining facts in litigation, and a court may require that information be sought by means that are "more convenient, less burdensome, or less expensive." *See* Fed. R. Civ. P. 26(b)(2)(C). Indeed, "[c]ourts generally refuse to compel the deposition of a government witness if the [requesting party] may obtain discovery by an alternative and less burdensome method to the government." *See, e.g., Gomez v. City of Nashua*, N.H., 126 F.R.D. 432, 436 (D. N.H. 1989). As discussed above (*see* Section 1), you have already obtained extensive document discovery from the DEA in Track One-A of the MDL. And, as discussed below (*see* Section 8), many of the documents you seek are available from other sources, including Defendants. You have not, however, explained why you need depositions from the DEA here.

Moreover, your testimony requests are burdensome not only because of the number of broad topics you have identified, but also because they seek testimony under Rule 30(b)(6), thus requiring the DEA to prepare witnesses on each of the 30 topics listed. *See Infinity Fluids, Corp. v. Gen. Dynamics Land Sys., Inc.*, No. CV 14-40089-TSH, 2015 WL 4498069, at \*2 (D. Mass. July 23, 2015) ("It is . . . unquestionably more burdensome to testify at a Rule 30(b)(6) deposition than an individual deposition, because the designee must educate himself on various matters that may not have been part of what he knows from his own experience."). These 30 topics seek information spanning a 24-year period and involving multiple components, offices, and divisions of the DEA. Because no one agency employee could possibly have knowledge of, or even prepare to speak to, all 30 of the topics on which you seek testimony, your requests effectively seek multiple 30(b)(6) deponents from the DEA, each of whom would be required to devote substantial time to prepare and sit for a deposition. Compliance with such an extraordinarily broad request for testimony imposes an even greater burden than that required for the production of documents because it not only requires not only that the DEA identify all responsive information but also that the 30(b)(6) deponents familiarize themselves that information. This, in turn, would have an adverse impact on government employees in the performance of their core mission and duties. *See* 28 C.F.R. § 16.26.



Laura Flahive Wu  
April 24, 2020  
Page 7

**5. Your Testimony Request Fails to Describe 30(b)(6) Topics with Reasonable Particularity.**

Your request also fails to describe the topics of the proposed depositions with “reasonable particularity” as required by Rule 30(b)(6) (requiring a subpoena to a governmental agency to “describe with reasonable particularity the matters for examination”). This reasonable particularity is necessary to permit appropriate preparation of the agency employees who would be deposed on behalf of the DEA. Your request seeks testimony concerning virtually every report, investigation, communication, and action by the DEA relating to opioids in West Virginia over a 24-year period, plus additional testimony on several topics that are *not* geographically limited to West Virginia. This does not comply with Rule 30(b)(6).

**6. Your Document and Testimony Requests Seek Law-Enforcement Sensitive Information.**

Much of the information that you seek through documents and testimony is protected from disclosure as law enforcement sensitive by DOJ’s regulations. Pursuant to 28 C.F.R. § 16.26(b)(5), the DEA is prohibited from releasing information, including through deposition testimony, if “[d]isclosure would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings or disclose investigative techniques and procedures the effectiveness of which would thereby be impaired.”

For example, your requests seek documents describing the “DEA’s policies and procedures and training” concerning investigations, the DEA’s use of ARCOS and SORS in the context of investigations, and files and communications relating to virtually every DEA investigation, open or closed, concerning opioids in West Virginia in the last 24 years. Your request for 30(b)(6) testimony on these topics raises the same concern. Much of the testimony would likely involve privileged and sensitive law enforcement matters which are not only beyond the scope of permissible discovery under Rule 26 of the Federal Rules of Civil Procedure but are also beyond the scope of matters which can be released under 28 C.F.R. § 16.26(b).

The release of such information could reveal the DEA’s investigative techniques and enable wrongdoers to avoid detection, which is prohibited by section 16.26(b)(5). Moreover, even if some subset of the requested information can be disclosed without compromising law enforcement interests, it will impose a significant additional burden on the DEA to identify and withhold law enforcement sensitive information.



Laura Flahive Wu  
April 24, 2020  
Page 8

**7. Your Requests Violate the Privacy Act, 5 U.S.C. § 552a**

Certain of your requests—in particular, document request 34, seeking Joseph Rannazzisi’s DEA personnel file—seek information that, if disclosed, would violate the Privacy Act and 28 C.F.R. § 16.25(b)(1), or otherwise cause an unwarranted invasion of personal privacy.

Congress enacted the Privacy Act of 1974, 5 U.S.C. § 552a, in order “to protect against invasion of an individual’s personal privacy by . . . providing individuals with more control over the gathering, dissemination, and accuracy of [government] agency information about themselves.” *Unger v. District Disclosure Office IRS*, No. 1:99-CV-698, 2000 U.S. Dist. LEXIS 16064, at \*5-6 (N.D. Ohio Sep. 18, 2000). Congress has made it clear that the personnel files, medical files, and other similar files involving federal employees are to be considered confidential. *See Department of Air Force v. Rose*, 425 U.S. 352, 372 (1976) (“Congressional concern for the protection of the kind of confidential personal data usually included in a personnel file is abundantly clear.”). The release of personally identifiable information from a federal system of records without the individual’s consent violates the Privacy Act. *Unger*, 2000 U.S. Dist. LEXIS 16064, at \*5-6. *See also* 5 U.S.C. § 552a(i) (improper production of such documents without the consent of the employee involved or an appropriate court order is a criminal offense under federal law).

Personnel files contain sensitive personal information. The Privacy Act generally prohibits the disclosure of such information without appropriate justification. *See* 5 U.S.C. § 552a(b). *See Regan-Touhy v. Walgreen Co.*, 526 F.3d 641, 648-49 (10th Cir. 2008) (“personnel files often contain sensitive personal information, just as pharmacy files do, and it is not unreasonable to be cautious about ordering their entire contents disclosed willy-nilly. Indeed, the Supreme Court has underscored that ‘the requirement of Rule 26(b)(1) that the material sought in discovery be ‘relevant’ should be firmly applied, and the district courts should not neglect their power to restrict discovery [to protect] ‘a party or person from annoyance, embarrassment, [or] oppression....’”) (quoted authority omitted). You make no proffer why such information is necessary and germane to the litigation. Indeed, the DEA could subject itself to a private lawsuit by any individual whose data are improperly released outside its routine use. *See, e.g., Kinman v. United States*, No. 1:16-CV-329, 2016 U.S. Dist. LEXIS 169447, at \*10 (S.D. Ohio Dec. 7, 2016) (stating that the Privacy Act “provides a private cause of action against federal agencies for violating the Act’s provisions”); *see also* 5 U.S.C. § 552a(g)(1).

**8. Your Requests Seek Information Available from Other Sources, Including Defendants.**

Several of your requests for documents and testimony seek information that is already in the Defendants’ possession, including information that was provided to the DEA by Defendants in the first instance. It is unreasonable for Defendants to seek this information from the DEA.

Laura Flahive Wu  
April 24, 2020  
Page 9

Availability from a more convenient source is a defense to a subpoena served on a non-party, particularly a subpoena served on a government agency that uses the data for law enforcement purposes. *See Ohio Bureau of Workers Comp. v. MDL Active Duration Fund, Ltd.*, No. 2:05-CV-0673, 2006 U.S. Dist. LEXIS 82560, at \*10-12 (S.D. Ohio 2006) (granting a motion to quash subpoena based on law enforcement privilege and availability of information from other sources).

It is apparent from the text of several of your document and testimony requests that Defendants already have the requested information, and so it is unreasonable and burdensome for Defendants to seek the same information from the DEA. For example, document request 36 seeks “[a]ll Documents and Communications between DEA registrants and the Office of Diversion Control’s Liaison and Policy Section relating to registrants’ obligations under 21 C.F.R. § 1301.74.” Several other requests seek communications between the DEA and one or more Defendants. Defendants should already have these communications in their possession and thus should not seek them from the DEA.

\* \* \*

The foregoing objections are not exhaustive, and DOJ and the DEA reserve the right to assert further objections in response to the requests as appropriate, including privileges and protections such as sovereign immunity, the attorney-client privilege, the work product doctrine, the deliberative process privilege, the investigative privilege, the informant’s privilege, and the need to withhold classified information.

After carefully considering your request, consulting with the DEA, applying all of the above factors, and reviewing the relevant procedural and substantive law, I have determined that your requests are unreasonably burdensome, cumulative, duplicative, and improper under the applicable substantive and procedural requirements. Therefore, I do not authorize the disclosure of the official information that you requested.

If you have further questions, please do not hesitate to contact Assistant United States Attorney Fred Westfall, Civil Chief, of my office ([Fred.Westfall@usa.doj.gov](mailto:Fred.Westfall@usa.doj.gov), 304-340-7246) or Trial Attorney Kelly Phipps of the United States Department of Justice, Civil Division ([Kelly.E.Phipps@usdoj.gov](mailto:Kelly.E.Phipps@usdoj.gov), 202-353-1284).



Laura Flahive Wu  
April 24, 2020  
Page 10

Sincerely,

A handwritten signature in black ink, appearing to read "Michael B. Stuart". The signature is fluid and cursive, with a large "M" and "S".

---

MICHAEL B. STUART  
United States Attorney  
Southern District of West Virginia  
Acting Under Authority Conferred by 28 U.S.C. § 515

FBW/fbwjr  
Enclosures

cc: xALLDEFENDANTS-MDL2804-Service@arnoldporter.com  
mdl2804discovery@motleyrice.com

# Exhibit 1



## COVINGTON

BEIJING BRUSSELS DUBAI FRANKFURT JOHANNESBURG  
LONDON LOS ANGELES NEW YORK PALO ALTO  
SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001-4956  
T +1 202 662 6000

### By Electronic Mail

February 21, 2020

Mr. Michael B. Stuart  
United States Attorney  
Robert C. Byrd US Courthouse  
300 Virginia Street  
Charleston, WV 25301  
Email: mike.stuart@usdoj.gov

**Re: *Touhy* Requests in *City of Huntington v. AmerisourceBergen Drug Corporation*, 3:17-01362 (S.D. W. Va.), and *Cabell County Commission v. AmerisourceBergen Drug Corporation*, 3:17-01665 (S.D. W. Va.)**

Dear Mr. Stuart:

I write on behalf of Defendants in the matters of *City of Huntington v. AmerisourceBergen Drug Corporation*, 3:17-01362, and *Cabell County Commission v. AmerisourceBergen Drug Corporation*, 3:17-01665, pending in the United States District Court for the Southern District of West Virginia. In connection with those lawsuits, we will subpoena documents and testimony from the Drug Enforcement Administration (“DEA”). Copies of the subpoenas and accompanying correspondence are attached for your reference as Exhibit 1 and Exhibit 2.

This letter is submitted pursuant to 28 C.F.R. § 16.21 *et seq.*, the Department of Justice *Touhy* regulations. Because these subpoenas are directed at DEA, compliance is subject to the *Touhy* process, and, for that reason, we have not effected formal service of process and hope that it will be unnecessary. The basis for this request is set forth below with reference to the requirements imposed by the *Touhy* regulations.

### **I. Summary of Information Sought and its Relevance to the Proceeding**

These cases, recently remanded from *In re: National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio), involve claims by the City of Huntington and Cabell County Commission against DEA-registered pharmaceutical distributors. Plaintiffs allege, among other things, that the distributors violated the federal Controlled Substances Act (“CSA”) and accompanying DEA regulations.

Given DEA’s role in investigating and combatting prescription drug abuse in the Appalachian region, the discovery Defendants seek from DEA is crucial to Defendants’ ability to defend against Plaintiffs’ allegations. For example, discovery concerning DEA’s investigation of

## COVINGTON

Robert C. Byrd US Courthouse  
February 21, 2020  
Page 2

unlawful diversion and communications regarding the source of any increase is crucial to responding to Plaintiffs' allegations regarding causation as well as assessing the reasonableness of Defendants' conduct. Likewise, discovery concerning DEA's use of suspicious order reports, ARCOS data, or any other communications from Defendants to combat the diversion or misuse of prescription opioids is critical to assessing the reasonableness of Defendants' conduct.

As summarized below, we request documents and testimony relating to Plaintiffs' allegations that Defendants violated duties arising under the CSA. Plaintiffs' allegations span a broad timeframe throughout which various DEA personnel interacted with Defendants and developed specialized knowledge of DEA practice and procedure.

### **A. Information Sought from DEA**

Defendants request documents and testimony pursuant to Federal Rule of Civil Procedure 30(b)(6) from DEA relating, but not limited to, the following topics:

- Documents submitted by DEA to the House Energy and Commerce Committee as part of its investigation that resulted in the report *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*;
- The determination of estimates of diversion for Prescription Opioids during the Relevant Time Period pursuant to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act);
- Efforts to utilize ARCOS data, suspicious order reports, or the West Virginia Controlled Substance Automated Prescription Program data to combat the diversion or misuse of Prescription Opioids in the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- The unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- Any arrests, investigations, and indictments for crimes relating to the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- Efforts to combat the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- Individuals or entities suspected or known to have unlawfully produced, transported, diverted, sold, and/or trafficked Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;



## COVINGTON

Robert C. Byrd US Courthouse  
February 21, 2020  
Page 3

- Efforts to suspend, revoke, or seek the suspension or revocation of registrations or licenses of, or fine or otherwise sanction any distributors, doctors, pharmacies, pharmacists, healthcare providers or other persons or entities because of the alleged diversion or trafficking of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- Recommendations for actions to be taken by DEA or any federal, state, or local agency within the City of Huntington, Cabell County, or any town, village, or city within Cabell County, to combat the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids;
- The structure and operation of the DEA within West Virginia, including but not limited to organizational charts and all Documents discussing the operation of DEA within West Virginia and DEA's staffing in West Virginia.
- The use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- Efforts to combat drug-related crime, respond to the opioid epidemic, or form a joint task force to combat the opioid epidemic;
- The inspection, audit, or investigation conducted by DEA of any Defendant located in or distributing to pharmacies in West Virginia, including inspections, audits, and investigations that did not lead to any further investigation or enforcement action;
- DEA's policies and procedures and training with respect to inspections, audits and/or investigations of registrations in West Virginia, and summary information of completed inspections, audits and/or investigations of licensees by year;
- DEA's use of the Suspicious Order Reporting System (SORS), ARCOS data, or any other communications from Defendants to combat the diversion or misuse of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- DEA's policies and procedures and training with respect to inspections, audits and/or investigations of registrations in West Virginia, and summary information of completed inspections, audits and/or investigations of licensees by year;
- The investigation of suspicious orders reported by Defendants for West Virginia pharmacies, hospitals, or other dispensers for the Relevant Time Period;
- DEA's use of ARCOS data to investigate West Virginia pharmacies, pharmacists, or health care providers for the Relevant Time Period;

## COVINGTON

Robert C. Byrd US Courthouse  
February 21, 2020  
Page 4

- Any action DEA took in response to the U.S. Department of Justice Office of the Inspector General's report entitled *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids* (September 2019);
- DEA's decision to establish only one Tactical Diversion Squad for West Virginia until 2016;
- The search and seizure warrant executed on Safescript Pharmacy #6 in the United States District Court for the Southern District of West Virginia, Huntington Division (3:12-mj-00010) (February 15, 2012);
- DEA's investigation of and decision to not prosecute Wendell Kent Freeman;
- Suspicious order reports for West Virginia pharmacies, hospitals, and other dispensers that were submitted directly to DEA field offices in West Virginia;
- DEA's efforts relating to diversion or misuse of prescription opioids in West Virginia;
- DEA's communications with any federal, state, or local agency regarding access to Suspicious Order Reporting System (SORs) and/or the ARCOS database;
- DEA's communications with or about the Healthcare Distribution Alliance (HDA) or Healthcare Distribution Management Association (HDMA);
- DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Huntington, Cabell County, or any township, village, or city within Cabell County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances;
- The determination of Aggregate Production Quotas for Prescription Opioids;
- DEA's communications concerning Government Accountability Office (GAO) relating to the following report: *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders*, GAO-20-118 (Washington, D.C.: January 2020); and
- DEA's instructions regarding the submission of suspicious order reports, including any and all Documents or Communications in which the DEA told a manufacturer or distributor to stop submitting suspicious order reports and/or excessive purchase reports.

## II. Disclosure is Warranted Under 28 C.F.R. § 16.26

Pursuant to DOJ's *Touhy* regulations, the Deputy or Associate Attorney General assesses the following considerations in determining whether disclosure is warranted:

## COVINGTON

Robert C. Byrd US Courthouse  
February 21, 2020  
Page 5

(1) Whether such disclosure is appropriate under the rules of procedure governing the case or matter in which the demand arose, and

(2) Whether disclosure is appropriate under the relevant substantive law concerning privilege.

28 C.F.R. § 16.26(a).

This request satisfies both of these considerations. As explained previously, the requested documents and testimony directly concern the allegations in this lawsuit. Plaintiffs allege Distributors violated regulatory duties arising under the CSA, and the requested information is relevant to determining the nature of the alleged regulatory duties, the reasonableness of Defendants' conduct, and the role of Defendants in causing the injuries alleged by Plaintiffs. Moreover, Defendants do not request privileged documents.

Additionally, DOJ's *Touhy* regulations prohibit disclosure, subject to certain exceptions, if any of the following factors exist:

(1) Disclosure would violate a statute, such as the income tax laws, 26 U.S.C. 6103 and 7213, or a rule of procedure, such as the grand jury secrecy rule, F.R.Cr.P., Rule 6(e),

(2) Disclosure would violate a specific regulation;

(3) Disclosure would reveal classified information, unless appropriately declassified by the originating agency,

(4) Disclosure would reveal a confidential source or informant, unless the investigative agency and the source or informant have no objection,

(5) Disclosure would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings or disclose investigative techniques and procedures the effectiveness of which would thereby be impaired,

(6) Disclosure would improperly reveal trade secrets without the owner's consent.

28 C.F.R. § 16.26(b).

This request is not intended to implicate any of these considerations. To the extent DOJ or DEA believe any of the requested information does implicate these considerations, Defendants are willing to work with DOJ, if possible, to narrow the scope of the request. The requested information is within the scope of ordinary subpoena practice and does not seek disclosure of information prohibited by statute or regulation, nor information that is classified



**COVINGTON**

Robert C. Byrd US Courthouse  
February 21, 2020  
Page 6

or that would reveal the source of an informant. To the extent Defendants request investigatory records compiled for law enforcement purposes, Defendants do not request investigatory records that would interfere with ongoing enforcement proceedings. Further, in abundance of caution and to avoid any concern that disclosure of investigatory records would reveal “investigative techniques and procedures the effectiveness of which would thereby be impaired,” Defendants request that the information be provided as highly confidential pursuant to the protective order governing this matter.

**III. Expedited Response**

We ask that you work with Defendants to establish a reasonable schedule for disclosure of the requested documents and completion of testimony prior to that date.

Please contact me directly at 202-662-5982 or lflahivewu@cov.com if you have any questions concerning this subpoena or require additional information.

Sincerely,

/s/Laura Flahive Wu  
Laura Flahive Wu

*Counsel for Defendant  
McKesson Corporation*

Attachments

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

---

**THE CITY OF HUNTINGTON,**

**Plaintiff,**

**v.**

**AMERISOURCEBERGEN DRUG  
CORPORATION, *et al.*,**

**Defendants.**

---

**Civil Action No. 3:17-01362**

---

**CABELL COUNTY COMMISSION,**

**Plaintiff,**

**v.**

**AMERISOURCEBERGEN DRUG  
CORPORATION, *et al.*,**

**Defendants.**

---

**Civil Action No. 3:17-01665**

**DEFENDANTS' NOTICE OF SUBPOENAS FOR TESTIMONY AND PRODUCTION  
OF DOCUMENTS TO THE U.S. DRUG ENFORCEMENT ADMINISTRATION**

PLEASE TAKE NOTICE that, pursuant to Rules 30 and 45 of the Federal Rules of Civil Procedure, Defendants will serve the attached subpoenas commanding testimony and the production of documents on the U.S. Drug Enforcement Administration. The DEA shall produce the requested documents by March 12, 2020, at Covington & Burling LLP, One CityCenter, 850 Tenth Street, NW, Washington, DC 20001. The deposition will be held at Covington & Burling LLP, One CityCenter, 850 Tenth Street, NW, Washington, DC 20001 on a mutually agreeable date to be determined, and it will continue from day to day until completed. It will be taken

pursuant to the Federal Rules of Civil Procedure and other applicable laws for all lawful purposes, including trial. The deposition will be taken before a person authorized to administer oaths and will be recorded by videotape and stenographic means. You are invited to attend and participate.

Dated: February 21, 2020

Respectfully submitted,

BY: /s/ Laura Flahive Wu  
Laura Flahive Wu  
COVINGTON & BURLING LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001-4956  
Telephone: (202) 662-5982  
lflahivewu@cov.com

*Counsel for Defendant McKesson  
Corporation*

/s/ Enu Mainigi  
Enu Mainigi  
WILLIAMS & CONNOLLY LLP  
725 Twelfth Street, N.W.  
Washington, DC 20005  
Telephone: (202) 434-5000  
Fax: (202) 434-5029  
emainigi@wc.com

*Counsel for Defendant Cardinal Health,  
Inc.*

/s/ Shannon E. McClure  
Shannon E. McClure  
REED SMITH LLP  
Three Logan Square  
1717 Arch Street, Suite 3100  
Philadelphia, PA 19103  
Telephone: (215) 851-8100  
Fax: (215) 851-1420  
smcclure@reedsmith.com

*Counsel for Defendant*



*AmerisourceBergen Drug Corporation*

**CERTIFICATE OF SERVICE**

I, Laura Flahive Wu, hereby certify that the foregoing document was served via email to all counsel of record.

/s/ Laura Flahive Wu  
LAURA FLAHIVE WU

# Exhibit 1



## UNITED STATES DISTRICT COURT

for the

Southern District of West Virginia

City of Huntington; Cabell County Commission

*Plaintiff*

v.

AmerisourceBergen Drug Corporation, et al.

*Defendant*

Civil Action No. 3:17-01362; 3:17-01665

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS  
OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: U.S. Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152

(Name of person to whom this subpoena is directed)

☒ **Production:** **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See Schedule A

Place: Covington & Burling LLP  
850 10th Street NW  
Washington, DC 20001

Date and Time:

03/12/2020 9:00 am

☐ **Inspection of Premises:** **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:

Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: \_\_\_\_\_

CLERK OF COURT

OR

\_\_\_\_\_  
Signature of Clerk or Deputy Clerk\_\_\_\_\_  
Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing (name of party) All Defendants  
McKesson Corporation, who issues or requests this subpoena, are:

Jeff Wakefield, 200 Capitol Street, Charleston, WV 25301, jwakefield@flahertylegal.com, (304) 347-4231

**Notice to the person who issues or requests this subpoena**

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 3:17-01362; 3:17-01665

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)*

I received this subpoena for *(name of individual and title, if any)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_.

☐ I served the subpoena by delivering a copy to the named person as follows: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I returned the subpoena unexecuted because: \_\_\_\_\_  
\_\_\_\_\_.

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also  
tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of  
\$ \_\_\_\_\_.

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_ 0.00 \_\_\_\_\_.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_  
\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc.:

**Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)****(c) Place of Compliance.**

**(1) For a Trial, Hearing, or Deposition.** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
  - (i) is a party or a party's officer; or
  - (ii) is commanded to attend a trial and would not incur substantial expense.

**(2) For Other Discovery.** A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

**(d) Protecting a Person Subject to a Subpoena; Enforcement.**

**(1) Avoiding Undue Burden or Expense; Sanctions.** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

**(2) Command to Produce Materials or Permit Inspection.**

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

**(3) Quashing or Modifying a Subpoena.**

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

- (i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

**(e) Duties in Responding to a Subpoena.**

**(1) Producing Documents or Electronically Stored Information.** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

**(2) Claiming Privilege or Protection.**

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

**(g) Contempt.**

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## SCHEDULE A

### Requests for Production of Documents to the Drug Enforcement Administration

#### DEFINITIONS

Notwithstanding any definition set forth below, each word, term, or phrase used in these Requests is intended to have the broadest meaning permitted under the Federal Rules of Civil Procedure and the Local Civil Rules for the U.S. District Court for the Southern District of West Virginia.

1. “You” and “Your” refers to the Drug Enforcement Administration (“DEA”) and all others acting or purporting to act on DEA’s behalf, including any employees, officers, committees, subcommittees, working groups, and joint task forces.
2. “Communication” means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
3. “Defendants” means all defendants named in *The City of Huntington v. AmerisourceBergen Drug Corporation*, 3:17-01362 (S.D. W. Va.), or *Cabell County Commission v. AmerisourceBergen Drug Corporation*, 3:17-01665 (S.D. W. Va.), as of the date of this notice.
4. “Document” has the full meaning ascribed to it by Federal Rule of Civil Procedure 34(a), and means the complete original (or complete copy where the original is unavailable) and each non-identical copy (where different from the original because of notes made on the copy or otherwise) of any writing or record, including, but not limited to, all written, typewritten, handwritten, printed, or graphic matter of any kind or nature, however produced or reproduced, any form of collected data for use with electronic data processing equipment, and any mechanical or electronic visual or sound recordings or text messages in Your possession, custody, or control. “Documents” include, but are not limited to, books, papers, contracts, memoranda, invoices, correspondence, notes, studies, reports, manuals, photographs, drawings, charts, graphs, data compilations, other writings, microfilm, microfiche, audio recordings, video recordings, electronic mail, and any other information stored in electronic form, and each different version or copy of each Document, including, but not limited to, drafts.
5. “Prescription Opioids” means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in West Virginia only through prescriptions filled by dispensers duly licensed and regulated by DEA.



6. “Illicit Opioids” means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not obtained from a licensed practitioner pursuant to a legitimate prescription. Illicit opioids include but are not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, counterfeit opioid medications, and Prescription Opioids that are diverted.
7. “DEA Registrant” or “Registrant” means Registrant as defined in 21 C.F.R. § 1300.01(b) (“any person who is registered pursuant to either section 303 or section 1008 of the [Controlled Substances] Act”).
8. “Registration” means Registration as defined in 21 C.F.R. § 1300.01(b) (“registration required and permitted by sections 303 or 1007 of the [Controlled Substances] Act”).
9. “Aggregate Production Quota” means the quantity of Prescription Opioids “necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks” per 21 C.F.R. § 1303.11.
10. “Suspicious Order Monitoring Program” means a system intended to aid in compliance with 21 C.F.R. § 1301.74 as defined by DEA to be required by 21 C.F.R. § 1301.74.

### **INSTRUCTIONS**

Should You consider any of the Documents requested to be confidential such that they should not be generally disseminated to the public or released to the press, we ask that You designate them as such under the Protective Orders in the MDL (copies attached) and the parties will deal with them accordingly.

To the extent You determine that any of the requests below implicate any type of law enforcement or investigative privilege, please identify which requests you believe implicate that privilege and please construe such requests to exclude Documents relating to current or ongoing investigations.

All of the following requests are intended to encompass Documents maintained in electronic or paper form, and “correspondence” or “Communications” include emails, letters or other papers, and memos reflecting oral Communications.

As these Documents will be shared with a large number of counsel and parties, we ask that You produce copies of them in electronic or paper form. Please let the undersigned know if there are charges or fees for searching or copying and, if so, also advise whether You will provide an invoice for the cost after production or if prepayment is required.

Unless otherwise indicated, the Relevant Time Period applicable to these requests is 1996 to the present.<sup>1</sup>

### **DOCUMENTS TO BE PRODUCED**

1. All Documents submitted by You to the House Energy and Commerce Committee as part of its investigation that resulted in the report *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, December 19, 2018, including but not limited to all Documents produced to the Committee, all written statements provided to Committee, and all notes, presentations, handouts and communications relating to the multiple briefings from DEA Staff to Committee Staff referenced in the Report.
2. All Documents and Communications concerning the determination of estimates of diversion for Prescription Opioids during the Relevant Time Period pursuant to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Pub. L. 115-271, 132 Stat. 3894. *See* [https://www.deadiversion.usdoj.gov/fed\\_regs/quotas/2019/fr0912.htm](https://www.deadiversion.usdoj.gov/fed_regs/quotas/2019/fr0912.htm).
3. All Documents describing, relating to, or reflecting efforts made by You to access or utilize ARCOS Data, Suspicious Order Reports, and/or West Virginia Controlled Substance Automated Prescription Program data to combat the diversion or misuse of Prescription Opioids in the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
4. All Documents referring or relating to the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
5. All Documents and data referring, tracking, or relating to any arrests, investigations, and indictments for crimes relating to the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
6. All Documents discussing, referring, or relating to Your efforts to combat the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
7. All Documents and Communications identifying, discussing, or relating to the individuals or entities You suspect or know have unlawfully produced, transported, diverted, sold, and/or

---

<sup>1</sup> Should the Court issue a ruling establishing a different time period for discovery, Defendants will revise the Relevant Time period accordingly.

trafficked Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.

8. All Documents referring or relating to Your efforts to suspend, revoke, or seek the suspension or revocation of registrations or licenses of, or fine or otherwise sanction any distributors, doctors, pharmacies, pharmacists, healthcare providers or other persons or entities because of the alleged diversion or trafficking of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
9. All Documents that state, discuss, reflect, or suggest recommendations for actions to be taken by You or any federal, state, or local agency within the City of Huntington, Cabell County, or any town, village, or city within Cabell County, to combat the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids.
10. Documents sufficient to show the structure and operation of the DEA within West Virginia, including but not limited to organizational charts and all Documents discussing the operation of DEA within West Virginia and DEA's staffing in West Virginia.
11. All Documents referring or relating to any Defendant regarding the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
12. All Documents and Communications between You and any federal, state, or local agency (including but not limited to the West Virginia Board of Pharmacy, the West Virginia Board of Medicine, the West Virginia Board of Osteopathic Medicine, the West Virginia Board of Dentistry, the West Virginia State Board of Examiners for Licensed Practical Nurses, the West Virginia State Board of Examiners for Registered Professional Nurses, the Department of Justice, the FBI, other federal, state, and local law enforcement entities), and the City of Huntington, Cabell County, or any town, village, or city within Cabell County regarding Illicit Opioids, Prescription Opioids, diversion, or the opioid epidemic. Included within this response are all Documents and Communications regarding efforts to combat drug-related crime, respond to the opioid epidemic, or form a joint task force to combat the opioid epidemic.
13. All Documents reflecting or relating to any completed inspection, audit, or investigation conducted by You of any Defendant located in or distributing to pharmacies in West Virginia, including inspections, audits, and investigations that did not lead to any further investigation or enforcement action. Defendants can provide a list of registration numbers for the relevant distribution centers, if requested.
14. All Documents reflecting or relating to DEA's policies and procedures and training with respect to inspections, audits and/or investigations of registrations in West Virginia, and summary information of completed inspections, audits and/or investigations of licensees by year.

15. All Documents reflecting or relating to the DEA's policies, procedures, and training with respect to distribution or dispensing controlled substances for the treatment of pain.
16. All Communication between DEA Headquarters and DEA field offices related to Your use of the Suspicious Order Reporting System (SORS), ARCOS data, or any other communications from Defendants to combat the diversion or misuse of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
17. All Documents relating to Your use of suspicious order reports submitted by Defendants to DEA Headquarters relating to West Virginia registrants, including but not limited to the transmittal of such suspicious order reports to DEA Diversion Investigators responsible for West Virginia and/or other federal, state or local government agencies.
18. All Documents related to any investigation of suspicious orders reported by Defendants for West Virginia pharmacies, hospitals, or other dispensers for the Relevant Time Period.
19. All Documents relating to Your use of ARCOS data or the West Virginia Controlled Substance Automated Prescription Program data to investigate West Virginia pharmacies, pharmacists, or health care providers for the Relevant Time Period.
20. All Documents and Communications relating to any proposed changes to 21 U.S.C. § 823, 21 C.F.R. § 1301.74, or any other DEA regulation and/or guidance with respect to suspicious orders for controlled substances, including but not limited to Your internal Communications and external Communications with registrants and the United States Congress.
21. All Documents and Communications relating to any action You took in response to the U.S. Department of Justice Office of the Inspector General's report entitled *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids* (September 2019), including but not limited to internal communications relating to the recommendation that DEA "establish regulations, policies, and procedures that specifically define what constitutes a suspicious order, as well as what information should be included in a suspicious order report."
22. All Documents and Communications relating to DEA's decision to establish only one Tactical Diversion Squad for West Virginia until 2016.
23. All Documents arising out of the search and seizure warrant executed on Safescript Pharmacy #6 in the United States District Court for the Southern District of West Virginia, Huntington Division (3:12-mj-00010) (February 15, 2012).
24. All Documents relating to Your investigation of and decision to not prosecute Wendell Kent Freeman.
25. Documents sufficient to identify those individuals at DEA responsible for receiving, analyzing, and disseminating suspicious order reports submitted to DEA Headquarters relating to the distribution of Prescription Opioids to West Virginia pharmacies, hospitals, and other dispensers during the Relevant Time Period.



26. All Documents relating to suspicious order reports for West Virginia pharmacies, hospitals, and other dispensers that were submitted directly to DEA field offices in West Virginia during the Relevant Time Period, and all actions taken resulting from the same.
27. All DEA files and records relating to diversion or misuse of Prescription Opioids in West Virginia, including but not limited to correspondence or complaints related to potential or actual diversion or misuse of Prescription Opioids, documents and correspondence reflecting any actions undertaken by DEA relating to such complaints, and any other records relating to such complaints.
28. All Documents and Communications with any federal, state, or local agency in or with jurisdiction over the City of Huntington, Cabell County, or any township, village, or city within Cabell County, and/or any distributor or manufacturer, regarding access to Suspicious Order Reporting System (SORS) and/or the ARCOS database.
29. All Documents or Communications concerning the DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Huntington, Cabell County, or any township, village, or city within Cabell County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances.
30. All Documents and Communications concerning the determination of Aggregate Production Quotas for Prescription Opioids during the Relevant Time Period.
31. All Documents concerning Communications with or about the Healthcare Distribution Alliance (HDA) or Healthcare Distribution Management Association (HDMA).
32. All Documents concerning Communications with or about the Government Accountability Office (GAO) relating to the following report: *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders*, GAO-20-118 (Washington, D.C.: January 2020).
33. All Documents DEA has identified or determined were retained by Joseph Rannazzisi upon the conclusion of his employment with DEA, as well as all documents concerning DEA's investigation of whether documents were retained by Mr. Rannazzisi upon the conclusion of his employment with DEA.
34. The complete personnel file relating to the employment of Joseph Rannazzisi by the DEA.
35. All Documents provided by the DEA or by any current or former employee of the DEA to the Washington Post and/or to 60 Minutes, and all Documents concerning DEA's investigation relating to Documents provided to the Washington Post and/or 60 Minutes.
36. All Documents and Communications between DEA registrants and the Office of Diversion Control's Liaison and Policy Section relating to registrants' obligations under 21 C.F.R. § 1301.74.

IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

**This document relates to:**

***All Cases***

**Case No.: 1:17-md-2804-DAP**

**Honorable Dan Aaron Polster**

**CASE MANAGEMENT ORDER NO. 2: PROTECTIVE ORDER**

**I. Scope of Order**

1. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the Court to enter the following Stipulated Protective Order (“Protective Order” or “Order”). Unless otherwise noted, this Order is also subject to the Local Rules of this District and the Federal Rules of Civil Procedure on matters of procedure and calculation of time periods. Unless otherwise stated, all periods of time provided for in this Order are calculated as calendar days

2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, captioned as *In re: National Prescription Opiate Litigation* (MDL No. 2804), Case No. 1:17-CV-2804, which includes any related actions that have been or will be originally filed in this Court, transferred to this Court, or removed to this Court and assigned there (“the Litigation”). All materials produced or adduced in the course of

discovery, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any Party to this Litigation (the “Producing Party”) to any other party or parties (the “Receiving Party”). This Protective Order is binding upon all the Parties to this Litigation, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.

3. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.

4. The entry of this Protective Order does not preclude any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).

5. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential.

## **II. Definitions**

7. Party. “Party” means any of the parties in this Litigation at the time this Protective Order is entered, including officers and directors of such parties. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Confidential Information and/or Highly Confidential

Information as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

8. Discovery Material. “Discovery Material” means any information, document, or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) (“Computerized Material”) is produced by any Party in such form, the Producing Party may designate such matters as confidential by a designation of “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” on the media. Whenever any Party to whom Computerized Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL is produced reduces such material to hardcopy form, that Party shall mark the hardcopy form with the corresponding “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” designation.

9. Competitor. Competitor means any company or individual, other than the Designating Party, engaged in the design; development; manufacture; regulatory review process; dispensing; marketing; distribution; creation, prosecution, pursuit, or other development of an interest in protecting intellectual property; and/or licensing of any product or services involving opioids; provided, however, that this section shall not be construed as limiting the disclosure of Discovery Material to an Expert in this Litigation, so long as the notice required under Paragraph 38 is provided to the Designating Party prior to any such disclosure where required, and so long as no Discovery Material produced by one Defendant is shown to any current employee or consultant of a different Defendant,



except as provided in Paragraphs 33 or 34.

10. Confidential Information. “Confidential Information” is defined herein as information that the Producing Party in good faith believes would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) on the basis that it constitutes, reflects, discloses, or contains information protected from disclosure by statute or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Health Information, protected law enforcement materials (including investigative files, overdose records, narcane, coroner’s records, court records, and prosecution files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as “Confidential.”

11. Highly Confidential Information. “Highly Confidential Information” is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not enumerated in Paragraphs 32 and 33, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective

Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as “Highly Confidential.”

12. Manufacturer Defendant: Manufacturer Defendant means any Defendant in this litigation that manufactures any Opioid Product for sale or distribution in the United States.

13. Distributor Defendant: Distributor Defendant means any Defendant in this litigation that distributes any Opioid Product in the United States other than a product they manufacture or license for manufacture.

14. Retail Defendant: Retail Defendant means any Defendant in this litigation that sells or distributes any Opioid Product directly to consumers in the United States.

15. Receiving Party. “Receiving Party” means a Party to this Litigation, and all employees, agents, and directors (other than Counsel) of the Party that receives Discovery Material from a Producing Party.

16. Producing Party. “Producing Party” means a Party to this Litigation, and all directors, employees, and agents (other than Counsel) of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party, subject to paragraph 3.

17. Protected Material. “Protected Material” means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that is designated as “Confidential” or “Highly Confidential” in accordance with this Protective Order.

18. Outside Counsel. “Outside Counsel” means any law firm or attorney who

represents any Party for purposes of this litigation.

19. In-House Counsel. “In-House Counsel” means attorney employees of any Party.

20. Counsel. “Counsel,” without another qualifier, means Outside Counsel and In- House Counsel.

21. Independent Expert. “Independent Expert” means an expert and/or independent consultant formally retained, and/or employed to advise or to assist Counsel in the preparation and/or trial of this Litigation, and their staff who are not employed by a Party to whom it is reasonably necessary to disclose Confidential Information or Highly Confidential Information for the purpose of this Litigation.

22. This Litigation. “This Litigation” means all actions in MDL No. 2804, *In re: National Prescription Opiate Litigation* or hereafter subject to transfer to MDL No. 2804.

### **III. Designation and Redaction of Confidential Information**

23. For each document produced by the Producing Party that contains or constitutes Confidential Information or Highly Confidential Information pursuant to this Protective Order, each page shall be marked “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER”, or “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER” or comparable notices.

24. Specific discovery responses produced by the Producing Party shall, if appropriate, be designated as Confidential Information or Highly Confidential Information by marking the pages of the document that contain such information with the notation “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER”, or “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER” or comparable notices.

25. Information disclosed through testimony at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party's receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or Highly Confidential Information and the "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed.

26. In accordance with this Protective Order, only the persons identified under Paragraphs 33 and 34, below, along with the witness and the witness's counsel may be present if any questions regarding Confidential Information or Highly Confidential are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

27. A Party in this Litigation may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" any document, material, or other information produced by, or testimony given by, any other person or entity that the designating Party reasonably believes



qualifies as the designating Party's Confidential Information or Highly Confidential Information pursuant to this Protective Order. The Party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party shall treat such information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same rights as a Producing Party under this Protective Order with respect to such information.

28. This Protective Order shall not be construed to protect from production or to permit the "Confidential Information" or "Highly Confidential Information" designation of any document that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

29. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, a Producing Party may redact certain Confidential or Highly Information from produced documents, materials or other things. The basis for any such redaction shall be stated in the Redaction field of the metadata produced pursuant to the Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Producing Party may redact:

(i) Personal Identifying Information. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees' names and business contact information) and (b) individuals in clinical studies or adverse event reports whose identity is protected by law.

(ii) Privileged Information. Information protected from disclosure by the attorney-client privilege, work product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.

(iii) Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 78, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce such documents in litigation.

30. To the extent any document, materials, or other things produced contain segregated, non-responsive Confidential or Highly Confidential Information concerning a Producing Party's non-opioid products (or, in the case of Plaintiffs, concerning programs, services, or agencies not at issue in this litigation), the Producing Party may redact that segregated, non-responsive, Confidential or Highly Confidential information except (a) that if a Producing Party's non-opioid product is mentioned in direct comparison to the Producing Party's opioid product, then the name and information about that product may not be redacted or (b) if the redaction of the name and information about the Producing Party's non-opioid product(s) would render the information pertaining to Producing Party's opioid product meaningless or would remove the context of the information about

Producing Party's opioid product, the name and information about the other product may not be redacted. Nothing in this paragraph shall restrict Plaintiffs' right and ability to request information about such other products nor restrict Defendants' right to object to or otherwise seek protection from the Court concerning any such request.

31. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients who were reported as experiencing adverse events that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as CONFIDENTIAL INFORMATION. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Producing Party.

#### **IV. Access to Confidential and Highly Confidential Information**

32. General. The Receiving Party and counsel for the Receiving Party shall not disclose or permit the disclosure of any Confidential or Highly Confidential Information to any third person or entity except as set forth in Paragraphs 33 and 34.

33. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 33.I) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;
- b. Vendor agents retained by the parties or counsel for the parties, provided

that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

- c. Individual Parties;
- d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph shall be deemed to permit the showing of one defendant's Confidential Information to an officer, director, or employee of another defendant, except to the extent otherwise authorized by this Order;
- e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- h. Any individual(s) who authored, prepared, or previously reviewed or received the information;



- i. To the extent contemplated by Case Management Order One, dated April 11, 2018 (Dkt. No. 232), those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation.
- j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- k. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;
- l. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification

contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order.; or

- m. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

34. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 34.j) and its contents shall not be disclosed to any person unless

that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel of any Plaintiff, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. Information designated as Highly Confidential by any Defendant may be disclosed to one In-House counsel of another Defendant, provided that the In-House counsel (i) has regular involvement in the Litigation, (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the individual completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In-House Counsel is reasonably necessary to the Litigation;
- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;;
- c. Individual Parties that have produced the designated information;
- d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- e. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

- f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- g. Any individual(s) who authored, prepared or previously reviewed or received the information;
- h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;
- j. Counsel for claimants litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient

agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant; or

- k. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Highly Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Highly Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

35. With respect to documents produced to Plaintiffs, documents designated as "HIGHLY CONFIDENTIAL" will be treated in the same manner as documents designated "CONFIDENTIAL," except that Plaintiffs may not disclose Highly Confidential Information to In-House Counsel (or current employees) of any Competitor of the Producing Party, except as otherwise provided in this Order or any other Order in this Litigation.



36. In the event that In-House Counsel (or current employees) of any Competitor of the Producing Party is present at the deposition of an employee or former employee of the Producing Party, prior to a document designated as Highly Confidential being used in the examination, such In-House Counsel (current employees) of any Competitor of the Producing Party shall excuse himself or herself from the deposition room without delaying or disrupting the deposition.

#### **V. Confidentiality Acknowledgment**

37. Each person required under this Order to complete the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound, shall be provided with a copy of this Protective Order, which he or she shall read, and, upon reading this Protective Order, shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Unless otherwise provided in this Order, Counsel for each Party shall maintain the Acknowledgments without giving copies to the other side. The Parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Protective Order, there will be no attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Protective Order, such disclosure will be pursuant to separate court order. Persons who come into contact with Confidential Information or Highly Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements, but must comply with the terms of this Protective Order.

## **VI. Litigation Experts and Consultants.**

38. Formally Retained Independent Experts and Consultants. Subject to the provisions of this Protective Order, all Confidential Information or Highly Confidential Information may be disclosed to any formally retained independent expert or consultant who has agreed in writing pursuant to Paragraph 37 or on the record of a deposition to be bound by this Protective Order. The party retaining an independent expert or consultant shall use diligent efforts to determine if the independent expert or consultant is currently working with or for a Competitor of a Producing Party in connection with a Competitor's opioid product. Prior to the initial disclosure of any information designated as Confidential Information or Highly Confidential Information to an expert or consultant who is currently working with or for a Competitor of the Producing Party in connection with a Competitor's opioid product, the party wishing to make such a disclosure ("Notifying Party") shall provide to counsel for the Producing Party in writing, which may include by e-mail, a statement that such disclosure will be made, identifying the general subject matter category of the Discovery Material to be disclosed, providing the nature of the affiliation with the Competitor entity and name of the Competitor entity, and stating the general purpose of such disclosure; the specific name of the formally retained independent expert or consultant need not be provided. The Producing Party shall have seven (7) days from its receipt of the notice to deliver to the Notifying Party its good faith written objections (if any), which may include e-mail, to such disclosure to the expert or consultant.

39. Absent timely objection, the expert or consultant shall be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order. Upon and pending resolution of a timely objection, disclosure to the expert or

consultant shall not be made. If the Notifying Party desires to challenge to the Producing Party's written objection to the expert or consultant, the Notifying Party shall so inform the Producing Party in writing, within ten (10) days of receipt of the Producing Party's written objection, of its reasons for challenging the objection. The expert or consultant shall then be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order after seven (7) days from receipt of the Producing Party's timely challenge to the written objection to the expert or consultant, unless within that seven day period, the Producing Party seeks relief from the Court pursuant to the procedures for discovery disputes set forth in Section 9(o) of Case Management Order One, or the Parties stipulate to an agreement. Once a motion is filed, disclosure shall not occur until the issue is decided by the Court and, if the motion is denied, the appeal period from the Court order denying the motion has expired. In making such motion, it shall be the Producing Party's burden to demonstrate good cause for preventing such disclosure.

## **VII. Protection and Use of Confidential and Highly Confidential Information**

40. Persons receiving or having knowledge of Confidential Information or Highly Confidential Information by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Confidential Information or Highly Confidential Information only as permitted by this Protective Order. Counsel shall take reasonable steps to assure the security of any Confidential Information or Highly Confidential Information and will limit access to such material to those persons authorized by this Protective Order.

41. Nothing herein shall restrict a person qualified to receive Confidential

Information and Highly Confidential Information pursuant to this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this Litigation and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order.

42. All persons qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order shall at all times keep all notes, abstractions, or other work product derived from or containing Confidential Information or Highly Confidential Information in a manner to protect it from disclosure not in accordance with this Protective Order, and shall be obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other thing, or portions thereof (and the information contained therein) are returned and surrendered pursuant to Paragraph 46. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.

43. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Protective Order to use Confidential Information or Highly Confidential Information and, in the course thereof, relying upon such information, provided that in rendering such advice, Counsel

shall not disclose any other Party's Confidential Information or Highly Confidential Information other than in a manner provided for in this Protective Order.

44. Nothing contained in this Protective Order shall prejudice in any way the rights of any Party to object to the relevancy, authenticity, or admissibility into evidence of any document or other information subject to this Protective Order, or otherwise constitute or operate as an admission by any Party that any particular document or other information is or is not relevant, authentic, or admissible into evidence at any deposition, at trial, or in a hearing

45. Nothing contained in this Protective Order shall preclude any Party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any Party or the Court.

46. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party.

47. If a Receiving Party learns of any unauthorized disclosure of Confidential Information or Highly Confidential Information, it shall immediately (a) inform the Producing Party in writing of all pertinent facts relating to such disclosure; (b) make its best effort to retrieve all copies of the Confidential Information or Highly Confidential Information; (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order; and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.



48. Unless otherwise agreed or ordered, this Protective Order shall remain in force after dismissal or entry of final judgment not subject to further appeal of this Litigation.

49. Within ninety (90) days after dismissal or entry of final judgment not subject to further appeal of this Litigation, or such other time as the Producing Party may agree in writing, the Receiving Party shall return all Confidential Information and Highly Confidential Information under this Protective Order unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the Parties agree to destruction to the extent practicable in lieu of return;<sup>1</sup> or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that Party elects to destroy the documents and certifies to the producing party that it has done so.

50. Notwithstanding the above requirements to return or destroy documents, Plaintiffs' outside counsel and Defendants' outside counsel may retain (1) any materials required to be retained by law or ethical rules, (2) one copy of their work file and work product, and (3) one complete set of all documents filed with the Court including those filed under seal, deposition and trial transcripts, and deposition and trial exhibits. Any retained Confidential or Highly Confidential Discovery Material shall continue to be protected under this Protective Order. An attorney may use his or her work product in subsequent litigation, provided that the attorney's use does not disclose or use Confidential Information or Highly Confidential Information.

---

<sup>1</sup> The parties may choose to agree that the Receiving Party shall destroy documents containing Confidential Information or Highly Confidential Information and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate and return e-mails (including attachments to e-mails) that may include Confidential Information or Highly Confidential Information, or Confidential Information or Highly Confidential Information contained in deposition transcripts or drafts or final expert reports.

### **VIII. Changes in Designation of Information**

51. If a Party through inadvertence produces any Confidential Information or Highly Confidential Information without labeling or marking or otherwise designating it as such in accordance with the provisions of this Protective Order, the Producing Party may give written notice to the Receiving Party that the document or thing produced is deemed “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” and should be treated as such in accordance with the provisions of this Protective Order, and provide replacement media, images, and any associated production information to conform the document to the appropriate designation and facilitate use of the revised designation in the production. The Receiving Party must treat such documents and things with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to receive such information shall not be deemed a violation of this Protective Order. Any Producing Party may designate as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” or withdraw a “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” designation from any material that it has produced consistent with this Protective Order, provided, however, that such redesignation shall be effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying Counsel for each Party in writing of such redesignation and providing replacement images bearing the appropriate description, along with the replacement media, images, and associated production information referenced above. Upon receipt of any redesignation and replacement image that designates material as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL”, the Receiving Party shall (i) treat such material in accordance with this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this

Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order. It is understood that the Receiving Party's good faith efforts to procure all copies may not result in the actual return of all copies of such materials.

52. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of the chosen designation. If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, it shall notify the Producing Party and the Receiving Party shall have seven (7) days from such notification to challenge the designation by commencing a discovery dispute under the procedures set forth in Section 9(o) of Case Management Order One. The ultimate burden of persuasion in any such challenge proceeding shall be on the Producing Party as if the Producing Party were seeking a Protective Order pursuant to Fed. R. Civ. P. 26(c) in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the even that a designation is changed by the Producing Party or by Court Order, the Producing Party shall provide replacement media,

images, and associated production information as provided above.

#### **IX. Inadvertent Production of Documents**

53. Non-Waiver of Privilege. The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure ("Privileged Information"). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of further showing under Federal Rule of Evidence 502(b) and shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the "Disclosing Party"). This Section shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d).

54. Notice of Production of Privileged Information. If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, and may demand that the Receiving Party return or destroy the Privileged Information. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

55. Recall of Privileged Information. If the Designating Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party's system:

- i. Locate each recalled document in the document review/production database and delete the record from the database;
- ii. If there is a native file link to the recalled document, remove the native file from the network path;
- iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents. Remove the line(s) corresponding to the document image(s) from the image load file;
- iv. Apply the same process to any additional copies of the document or database, where possible;
- v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as



described herein;

vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the receiving party shall discard the original production media; or (ii) allow the receiving party to retain the original production media, in which case the receiving party shall take steps to ensure that the recalled document will not be used; and

vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

56. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

57. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted ("Clawed-Back Information"), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information. Within 14 days after receiving the Disclosing Party's privilege log with respect to such Clawed-Back Information, a receiving party may notify the Disclosing Party in writing of an objection to a claim of privilege or work-product protection with respect to the Clawed-Back Information. Within 14 days of the receipt of such notification, the Disclosing Party

and the objecting party shall meet and confer in an effort to resolve any disagreement concerning the Disclosing Party's privilege or work-product claim with respect to such Clawed-Back Information. The parties may stipulate to extend the time periods set forth in this paragraph.

58. If, for any reason, the Disclosing Party and Receiving Party (or parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Court pursuant to the procedures set forth in Case Management Order One. The Disclosing Party bears the burden of establishing the privileged or protected nature of any Privileged Information.

59. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

60. In the event any prior order or agreement between the parties and/or between the parties and a non-party concerning the disclosure of privileged and/or work product protected materials conflicts with any of the provisions of this Order, the provisions of this Stipulated Order shall control.

61. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Disclosing Party that such materials have been produced.

#### **X. Filing and Use at Trial of Protected Material**

62. Only Confidential or Highly Confidential portions of relevant documents

are subject to sealing. To the extent that a brief, memorandum, or pleading references any document designated as Confidential or Highly Confidential, then the brief, memorandum or pleading shall refer the Court to the particular exhibit filed under seal without disclosing the contents of any confidential information. If, however, the confidential information must be intertwined within the text of the document, a party may timely move the Court for leave to file both a redacted version for the public docket and an unredacted version for sealing.

63. Absent a Court-granted exception based upon extraordinary circumstances, any and all filings made under seal shall be submitted electronically and shall be linked to this Stipulated Protective Order or other relevant authorizing order. If both redacted and unredacted versions are being submitted for filing, each version shall be clearly named so there is no confusion as to why there are two entries on the docket for the same filing.

64. If the Court has granted an exception to electronic filing, a sealed filing shall be placed in a sealed envelope marked "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER." The sealed envelope shall display the case name and number, a designation as to what the document is, the name of the party on whose behalf it is submitted, and the name of the attorney who has filed the sealed document. A copy of this Stipulated Protective Order, or other relevant authorizing order, shall be included in the sealed envelope.

65. A Party that intends to present Confidential Information or Highly Confidential Information at a hearing shall bring that issue to the Court's and Parties' attention without disclosing the Confidential Information or Highly Confidential Information. The Court may thereafter make such orders, including any stipulated orders, as are necessary to govern the use of Confidential Information or Highly Confidential Information

at the hearing. The use of any Confidential Information or Highly Confidential Information at trial shall be governed by a separate stipulation and/or court order.

**XI. Information or Highly Confidential Information Requested by Third Party;  
Procedure Following Request.**

66. If any person receiving Discovery Material covered by this Protective Order (the “Receiver”) is served with a subpoena, a request for information, or any other form of legal process that purports to compel disclosure of any Confidential Information or Highly Confidential Information covered by this Protective Order (“Request”), the Receiver must so notify the Designating Party, in writing, immediately and in no event more than five (5) court days after receiving the Request. Such notification must include a copy of the Request.

67. The Receiver also must immediately inform the party who made the Request (“Requesting Party”) in writing that some or all the requested material is the subject of this Protective Order. In addition, the Receiver must deliver a copy of this Protective Order promptly to the Requesting Party.

68. The purpose of imposing these duties is to alert the interested persons to the existence of this Protective Order and to afford the Designating Party in this case an opportunity to protect its Confidential Information or Highly Confidential Information. The Designating Party shall bear the burden and the expense of seeking protection of its Confidential Information or Highly Confidential Information, and nothing in these provisions should be construed as authorizing or encouraging the Receiver in this Litigation to disobey a lawful directive from another court. The obligations set forth in this paragraph remain in effect while the Receiver has in its possession, custody or control Confidential Information or Highly Confidential Information by the other Party in this Litigation.

69. Materials that have been designated as Confidential or Highly Confidential Discovery Material shall not be provided or disclosed to any third party in response to a request under any public records act, or any similar federal, state or municipal law (collectively, the “Public Disclosure Laws”), and are exempt from disclosure pursuant to this Protective Order. If a Party to this Litigation receives such a request, it shall (i) provide a copy of this Protective Order to the Requesting Party and inform it that the requested materials are exempt from disclosure and that the Party is barred by this Protective Order from disclosing them, and (ii) promptly inform the Designating Party that has produced the requested material that the request has been made, identifying the name of the Requesting Party and the particular materials sought. If the Designating Party seeks a protective order, the Receiving Party shall not disclose such material until the Court has ruled on the request for a protective order. The restrictions in this paragraph shall not apply to materials that (i) the Designating Party expressly consents in writing to disclosure; or (ii) this Court has determined by court order to have been improperly designated as Confidential or Highly Confidential Discovery Material. The provisions of this section shall apply to any entity in receipt of Confidential or Highly Confidential Discovery Material governed by this Protective Order. Nothing in this Protective Order shall be deemed to (1) foreclose any Party from arguing that Discovery Material is not a public record for purposes of the Public Disclosure Laws; (2) prevent any Party from claiming any applicable exemption to the Public Disclosure Laws; or (3) limit any arguments that a Party may make as to why Discovery Material is exempt from disclosure.

## **XII.HIPAA-Protected Information**

70. General. Discovery in this Litigation may involve production of “Protected Health Information” as that term is defined and set forth in 45 C.F.R. § 160.103, for which special protection from public disclosure and from any purpose other than prosecuting this Action is warranted

71. “Protected Health Information” shall encompass information within the scope and definition set forth in 45 C.F.R. § 160.103 that is provided to the Parties by a covered entity as defined by 45 C.F.R. § 160.103 (“Covered Entities”) or by a business associate of a Covered Entity as defined by 45 C.F.R. § 160.103 (“Business Associate”) in the course of the Litigation, as well as information covered by the privacy laws of any individual states, as applicable.

72. Any Party who produces Protected Health Information in this Litigation shall designate such discovery material “Confidential Protected Health Information” in accordance with the provisions of this Protective Order.

73. Unless otherwise agreed between counsel for the Parties, the designation of discovery material as “Confidential Protected Health Information” shall be made at the following times: (a) for documents or things at the time of the production of the documents or things; (b) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and other documents, at the time of the service or filing, whichever occurs first; (c) for testimony, at the time such testimony is given by a statement designating the testimony as “Confidential Protected Health Information” made on the record or within thirty (30) days after receipt of the transcript of the deposition. The designation of discovery material as “Confidential Protected Health



Information” shall be made in the following manner: (a) for documents, by placing the notation “Confidential Protected Health Information” or similar legend on each page of such document; (b) for tangible things, by placing the notation “Confidential Protected Health Information” on the object or container thereof or if impracticable, as otherwise agreed by the parties; (c) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and any other documents containing Protected Health Information, by placing the notation “Confidential Protected Health Information” both on the face of such document and on any particular designated pages of such document; and (d) for testimony, by orally designating such testimony as being “Confidential Protected Health Information” at the time the testimony is given or by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days after receipt of the certified transcript of the deposition.

74. Pursuant to 45 C.F.R. § 164.512(e)(1), all Covered Entities and their Business Associates (as defined in 45 C.F.R. § 160.103), or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to the Action to those persons and for such purposes as designated in herein. Further, all Parties that are entities subject to state privacy law requirements, or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to this Action to those persons and for such purposes as designated in herein. The Court has determined that disclosure of such Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more parties to the proceedings.

75. The Parties shall not use or disclose Protected Health Information for any purpose other than the Litigation, including any appeals. The Parties may, inter alia, disclose Protected Health Information to (a) counsel for the Parties and employees of counsel who have responsibility for the Litigation; (b) the Court and its personnel; (c) Court reporters; (d) experts and consultants; and (e) other entities or persons involved in the Litigation.

76. Within sixty days after dismissal or entry of final judgment not subject to further appeal, the Parties, their counsel, and any person or entity in possession of Protected Health Information received pursuant to this Order shall destroy or return to the Covered Entity or Business Associate such Protected Health Information.

77. Nothing in this Order authorizes the parties to obtain Protected Health Information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or any other lawful process.

**XIII. Information Subject to Existing Obligation of Confidentiality Independent of this Protective Order.**

78. In the event that a Party is required by a valid discovery request to produce any information held by it subject to an obligation of confidentiality in favor of a third party, the Party shall, promptly upon recognizing that such third party's rights are implicated, provide the third party with a copy of this Protective Order and (i) inform the third party in writing of the Party's obligation to produce such information in connection with this Litigation and of its intention to do so, subject to the protections of this Protective Order; (ii) inform the third party in writing of the third party's right within fourteen (14) days to seek further protection or other relief from the Court if, in good faith, it believes such information to be confidential under the said obligation and either objects to the Party's

production of such information or regards the provisions of this Protective Order to be inadequate; and (iii) seek the third party's consent to such disclosure if that third party does not plan to object. Thereafter, the Party shall refrain from producing such information for a period of fourteen (14) days in order to permit the third party an opportunity to seek relief from the Court, unless the third party earlier consents to disclosure. If the third party fails to seek such relief, the Party shall promptly produce the information in question subject to the protections of this Protective Order, or alternatively, shall promptly seek to be relieved of this obligation or for clarification of this obligation by the Court.

#### **XIV. Miscellaneous Provisions**

79. Nothing in this Order or any action or agreement of a party under this Order limits the Court's power to make any orders that may be appropriate with respect to the use and disclosure of any documents produced or use in discovery or at trial.

80. Nothing in this Protective Order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.

81. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the Producing Party may immediately apply to obtain injunctive relief against any person violating or threatening to violate any of the terms of this Protective Order, and in the event the Producing Party shall do so, the respondent person, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the Producing Party possesses an adequate remedy at law.

82. This Protective Order shall not be construed as waiving any right to assert a claim of privilege, relevance, or other grounds for not producing Discovery

Material called for, and access to such Discovery Material shall be only as provided for by separate agreement of the Parties or by the Court.

83. This Protective Order may be amended without leave of the Court by agreement of Outside Counsel for the Parties in the form of a written stipulation filed with the Court. The Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of this Litigation.

84. Notwithstanding any other provision in the Order, nothing in this Protective Order shall affect or modify Defendants' ability to review Plaintiffs' information and report such information to any applicable regulatory agencies.

85. This Order is entered based on the representations and agreements of the parties and for the purpose of facilitating discovery. Nothing herein shall be construed or presented as a judicial determination that any documents or information designated as Confidential or Highly Confidential by counsel or the parties is subject to protection under Rule 26(c) of the Federal Rules of Civil Procedure or otherwise until such time as the Court may rule on a specific document or issue.

**IT IS SO ORDERED.**

Dated: 5/15/18

/s/Dan Aaron Polster  
Honorable Dan Aaron Polster  
United States District Judge

IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

**This document relates to:**

***All Cases***

**Case No.: 1:17-md-2804-DAP**

**Honorable Dan Aaron Polster**

**EXHIBIT A TO CASE MANAGEMENT ORDER NO. \_\_\_\_\_**

**ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND BY PROTECTIVE ORDER**

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Protective Order (CMO No. \_\_) that was issued by the United States District Court for the Northern District of Ohio on \_\_\_\_\_, 2018 in *In re: National Prescription Opiate Litigation* (the "Protective Order").

I agree to comply with and to be bound by all the terms of the Protective Order, and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to the Protective Order to any person or entity except in strict compliance with the provisions of the Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the Northern District of Ohio for the purposes of enforcing terms of the Protective Order, even if such enforcement proceedings occur after termination of these proceedings.

Date:\_\_\_\_\_

City and State where sworn and signed:\_\_\_\_\_

Printed Name:\_\_\_\_\_

Signature:\_\_\_\_\_



**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>IN RE NATIONAL PRESCRIPTION</b>	)	<b>CASE NO. 17-MD-2804</b>
<b>OPIATE LITIGATION</b>	)	
	)	<b>SPECIAL MASTER COHEN</b>
<b>This document relates to:</b>	)	
<i>All Cases</i>	)	
	)	<b>AMENDMENTS TO CMO NO. 2</b>
	)	<b>RE: CONFIDENTIALITY AND</b>
	)	<b>PROTECTIVE ORDER</b>

The parties have agreed to make certain amendments to various paragraphs contained in the Court's Case Management Order No. 2 (docket no. 441) which address confidentiality and Protective Order issues. The parties submitted other proposed amendments upon which they could not agree. The Special Master now adopts the parties' agreed-upon revisions and also resolves the parties' disagreements, and amends CMO-2 accordingly, as set out in the attached document.

**RESPECTFULLY SUBMITTED,**

/s/ David R. Cohen  
**David R. Cohen**  
**Special Master**

**Dated:** September 29, 2019

AMENDMENTS TO CONFIDENTIALITY & PROTECTIVE ORDER PROVISIONS  
OF CMO NO. 2 (docket no. 441)

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential. Parties shall not be overly broad in designating materials as Confidential or Highly Confidential under this Protective Order. If a Party is repetitively, overly broad in designating materials as Confidential or Highly Confidential, that Party risks having large categories of such designations denied protection. The Court expects and will assume that the attorney submitting the designation has reviewed it and does so subject to Rule 11.

10. Confidential Information. “Confidential Information” is defined herein as information that the Producing Party in good faith believes would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) on the basis that it constitutes, reflects, discloses, or contains information protected from disclosure by statute, or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Information, protected law enforcement materials (including investigative files, overdoes records, Narcan records, coroner’s records, court records, and prosecution files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Producing Party shall do so only after review of the documents or information by an attorney who has, in good faith, determined that the material would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the material is not otherwise publicly available, and that the material is not “stale” or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and rulings of the Special Master and the Court. Nothing herein shall be construed to allow for global designations of all documents as “Confidential.”

11. Highly Confidential Information. “Highly Confidential Information” is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not enumerated in Paragraphs 32 and 33, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so only after review of the documents or information by an attorney who has, in good faith, determined that the material would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the Producing Party has made reasonable efforts to keep the material confidential, that the material is not otherwise publicly available, and that the material is not “stale” or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and rulings of the Special Master and the Court. Nothing herein shall be construed to allow for global designations of all documents as “Highly Confidential.”

25. Information disclosed through testimony at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party's receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "HIGHLY CONFIDENTIAL-SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or Highly Confidential Information and the "HIGHLY CONFIDENTIAL-SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed. Any Confidential or Highly Confidential designations of deposition testimony by a party shall occur only if an attorney for that party has, in good faith, determined that the material is entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the Producing Party has made reasonable efforts to keep the material confidential, that the material is not otherwise publicly available, and that the material is not "stale" or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and the rulings of the Special Master and the Court. The Designating Party shall make page and line designations of deposition testimony; global designation of deposition testimony as Confidential or Highly Confidential is not permitted.

26. In accordance with this Protective Order, only the persons identified under Paragraphs 33 and 34 below, along with the witness and the witness's counsel, may be present if any questions regarding Confidential Information or Highly Confidential Information are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

27. A Party in this Litigation may designate as "Confidential" or "Highly Confidential" any document, material, or other information produced by, or testimony given by, any other person or entity that the designating Party reasonably believes qualifies as the designating Party's Confidential Information or Highly Confidential Information pursuant to this Protective Order. Any such designation may only be made after an attorney for the Designating Party has, in good faith, determined that the material would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the Producing Party has made reasonable efforts to keep the material confidential, that the material is not otherwise publicly available, and that the material is not "stale" or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and rulings of the Special Master and the Court. The Party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party shall treat such

information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same duties and rights as a Producing Party under this Protective Order with respect to such information.

28. This Protective Order shall not be construed to protect from production any document, or to permit the “Confidential Information” or “Highly Confidential Information” designation of any document, that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

29. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, a Producing Party may redact certain Confidential or Highly Confidential Information from produced documents, materials or other things. The basis for any such redaction shall be stated in the Redaction field of the document and/or in the metadata produced pursuant to the Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Producing Party may redact or de-identify:

(i) Personal Identifying Information. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees’ names and business contact information), (b) individuals in clinical studies or adverse event reports whose identity is protected by law, (c) undercover law enforcement personnel and confidential informants, and (d) patient identified information that is protected by 42 CFR 2.12 and associated regulations consistent with the Order Governing Production of Medical and Pharmacy Claims Data in Track One Cases [Dkt. 1421].

(ii) Privileged Information. Information protected from disclosure by the attorney-client privilege, work-product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.

(iii) Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 78, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce documents in litigation.

Plaintiffs may withhold or redact the following specific protected information: (a) records of ongoing criminal investigations, and (b) records or information provided to the party by DEA, FBI, or other state or federal law enforcement agency that such agency designates is of a sensitive nature. The fact of redacting or withholding does not create a presumption that the redaction or withholding is valid, and Receiving Parties can challenge redactions freely after providing

appropriate notice to the Producing Party and (if applicable) the agency asserting the privilege or confidentiality redaction.

33. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 33.L) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;
- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- c. Individual Parties;
- d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph shall be deemed to permit the showing of one defendant's Confidential Information to an officer, director, or employee of another defendant, except to the extent otherwise authorized by this Order;
- e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- h. Any individual(s) who authored, prepared, or previously reviewed or received the information;
- i. To the extent contemplated by Case Management Order One, dated April 11, 2018 (Dkt. No. 232), those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation.
- j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the

Designating Party may request a meet and confer and may seek a protective order from the Court.

- k. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgment because such counsel is bound by the terms of this Protective Order;
- l. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, distribution, or dispensing of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgments and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant; provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order; or
- m. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

34. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 34.j) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. Information designated as Highly Confidential by any Defendant may be disclosed to In-House Counsel of another Defendant, provided that the In-House Counsel (i) has regular involvement in the Litigation (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the individual completes the certification contained in Exhibit



A, Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential Information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In-House Counsel is reasonably necessary to the Litigation;

- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- c. Individual Parties that have produced the designated information;
- d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- e. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- g. Any individual(s) who authored, prepared, or previously reviewed or received the information;
- h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgment because such counsel is bound by the terms of this Protective Order;
- j. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, distribution, or dispensing of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgments and will receive Confidential and Highly Confidential Information pursuant to this Order

and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order; or

- k. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

46. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party. To the extent that a Producing Party's Confidential or Highly Confidential Information becomes part of the public record in this proceeding, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public through the Court record, the specific testimony, document excerpts, or other evidence will become and remain public. However, a Receiving Party shall not unnecessarily attempt to insert materials designated as Confidential or Highly Confidential into the Court record solely for purposes of making them public. Once information is made public, it is not confidential even if continued to be marked as such by the Producing Party, and the Receiving Party may freely use such information. A Receiving Party does not need to challenge Confidential or Highly Confidential designations of specific testimony, documents, or other evidence excerpts that become part of the public record in this proceeding. A Receiving Party can also challenge a designation for other testimony or portions of the excerpted document or other evidence as set forth in paragraph 52 below.

52. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document or deposition are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing, of its reasons why the confidentiality designation was not proper and must: (a) give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of the chosen designation, and (b) offer to provide the Producing Party with multiple alternatives (dates and times) to meet and confer during the seven (7) day period following the date of the

Receiving Party's written challenge notification. Thereafter, if a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, it shall notify the Producing Party, and the Receiving Party shall have seven (7) days from such notification to challenge the designation with the Court or Special Master. These time periods may be modified in emergent circumstances, as agreed to by the Challenging and Designating Parties, or as ordered by the Special Master or the Court. The ultimate burden of persuasion in any such challenge proceeding shall be on the Producing Party as if the Producing Party were seeking a Protective Order pursuant to Fed. R. Civ. P. 26(c) in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the event that a designation is changed by the Producing Party or by Court Order, the Producing Party shall provide replacement media, images, and associated production information as provided above. The parties are hereby notified that Discovery Ruling No. 20 Regarding Confidentiality Designations (Doc. 1650), as well as the "ARCOS Ruling" by the Sixth Circuit Court of Appeals (docket no. 1710), provide relevant legal standards, principles, and examples which should be followed and/or used as guidance relative to disputes over materials designated as Confidential or Highly Confidential at the discovery stage of the litigation.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>IN RE NATIONAL PRESCRIPTION</b>	)	<b>CASE NO. 17-MD-2804</b>
<b>OPIATE LITIGATION</b>	)	
	)	<b>SPECIAL MASTER COHEN</b>
<b>This document relates to:</b>	)	
<b>All Cases</b>	)	
	)	<b>AMENDMENT TO CMO NO. 2</b>
	)	<b><u>RE: INADVERTENT PRODUCTION</u></b>

The parties have agreed to make certain amendments to “Section IX. Inadvertent Production of Documents,” contained in the Court’s Case Management Order No. 2 (docket no. 441). The Court approves these amendments, which are set out in the attached document.

**RESPECTFULLY SUBMITTED,**

/s/ David R. Cohen

**David R. Cohen**  
**Special Master**

**Dated:** September 29, 2019

REPLACING SECTION IX OF CMO NO. 2 (docket no. 441)

**IX. Inadvertent Production of Documents**

53. Non-Waiver of Privilege. The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure (“Privileged Information “). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of further showing under Federal Rule of Evidence 502(b) and, pursuant to Federal Rule of Evidence 502(d), shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the “Disclosing Party”). This Section shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(b) and 502(d).

54. Notice of Production of Privileged Information.

a. Notice by Designating Party. If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, shall identify the type of privilege claimed, and may demand that the Receiving Party return or destroy the Privileged Information.

b. Notice by Receiving Party. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

55. Recall of Privileged Information. If the Designating Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party’s system:

- i. Locate each recalled document in the document review/production database and delete the record from the database;
- ii. If there is a native file link to the recalled document, remove the native file from the network path;

- iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents. Remove the line(s) corresponding to the document image(s) from the image load file;
- iv. Apply the same process to any additional copies of the document or database where possible;
- v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as described herein;
- vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the receiving party shall discard the original production media; or (ii) allow the receiving party to retain the original production media, in which case the receiving party shall take steps to ensure that the recalled document will not be used; and
- vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

56. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

57. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted ("Clawed-Back Information"), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information.

58. If, for any reason, the Designating Party and Receiving Party (or parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Special Master pursuant to the procedures set forth in Case Management Order One and established by the Special Master. The Designating Party bears the burden of establishing the privileged or protected nature of any Privileged Information. For circumstances where the Parties are unable to reach an agreement, the procedure for submission to the Special Master is as follows:

- i. Receiving Party shall file its Motion to Compel and request for *in camera* submission to the Special Master with carbon copy to include only counsel for Receiving Party and Designating Party;



- ii. Designating Party shall file its opposition on a schedule agreed to by the Designating and Receiving Parties or as set by the Special Master, with carbon copy to Receiving Party's counsel;
- iii. The Receiving Party shall file its reply (if any) on a schedule agreed to by the Designating and Receiving Parties or as set by the Special Master, with carbon copy to include only counsel for the Receiving Party and the Designating Party;
- iv. If necessary, a hearing shall be conducted just between the Designating Party, the Receiving Party, and the Special Master.

59. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

60. [REMOVED BY AGREEMENT OF THE PARTIES]

61. Nothing in this Order overrides an attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the other Party that such materials have been produced.

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION OPIATE  
LITIGATION**

This document relates to:

*“Track Two Cases”*

**MDL No. 2804**

**Case No. 17-md-2804**

**Special Master David Cohen**

**PROTECTIVE ORDER REGARDING DISCLOSURE  
BY PLAINTIFFS OF CONFIDENTIAL MEDICAL RECORDS**

WHEREAS, Distributor Defendants<sup>1</sup> served discovery upon the Track Two bellwether Plaintiffs which potentially requires the disclosure of protected health information governed by the Health Insurance Portability and Accountability Act of 1996 (hereinafter referred to as “HIPAA”); *R.K. v. St. Mary's Med. Ctr., Inc.*, 229 W. Va. 712, 735 S.E.2d 715 (2012); and

WHEREAS, this Court has addressed procedural safeguards to such disclosure throughout this litigation. *See e.g., Case Management Order No. 2: Protective Order* (Doc #: 441) (Doc #: 1357); *Track One Discovery Order Regarding Health-Related Information* (Doc #: 703); *Discovery Ruling No. 7* (Doc #: 1051); *November 21, 2018 Order* (Doc #: 1147); *Order Governing Production of Medical and Pharmacy Claims Data in Track One Cases* (Doc #: 1421); *Order Governing Production of Non-Party OptumRx, Inc.'s Pharmacy Claims Data for Track One Cases* (Doc #: 1635); *Order Governing Production Of Non-Party Humana Health Plan of Ohio, Inc.'s Medical And Pharmacy Claims Data For Track One Cases* (Doc #: 1641); *Amendment to CMO*

---

<sup>1</sup> The Distributor Defendants are AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation.

*No. 2 Re. Confidentiality and Protective Order* (Doc # 2688); *Amendment to CMO No. 2 Re: Inadvertent Production* (Doc #: 2687); *Agreed Order Governing Privilege* (Doc #: 2882); and

WHEREAS, the bellwether Plaintiffs desire to efficiently advance this litigation while preserving the privacy rights of the general public; and

WHEREAS, federal law provides this Court with the authority to compel the disclosure of protected health information while providing adequate safeguards; and

WHEREAS, the Plaintiffs and Distributor Defendants agree to the provisions below; now therefore

IT IS HEREBY ORDERED that the following provisions shall govern the production of protected health information in the Track Two Cases:

1. **Findings.** The Court hereby makes the following findings with respect to the production of protected health information:

- a. Good cause exists for the entry of this Order.
- b. Alternative methods of obtaining this information are not available or would not be effective.
- c. The public interest and the need for disclosure of this information, subject to the restrictions set forth herein, outweigh the potential injury to the patient, the physician-patient relationship, and the treatment services.
- d. The bellwether Plaintiffs shall produce relevant protected health information not implicated by Title 42, Part 2 of the Code of Federal Regulations ("Part 2"), without redaction.

e. Only those individuals who require the information for purposes of this litigation (as described below) may receive protected health information produced pursuant to this Order.

f. The procedures set forth herein are necessary to limit disclosure for the protection of the patient, the physician-patient relationship, and the treatment services.

3. **Designation.** Protected health information produced pursuant to this Order shall be produced with the following legend appearing in either the title of the electronic file or on the face of the document: "HIPAA PROTECTED HEALTH INFORMATION - ACCESS RESTRICTED TO ATTORNEYS AND EXPERTS."

4. **Restrictions on Disclosure.** All parties shall safeguard and maintain the confidentiality of this information pursuant to the terms of the HIPAA protective order (*see* docket no. 441, CMO-2 at 32-34), and shall limit disclosure to attorneys and experts for the parties, unless otherwise ordered by the Court. Specifically, no person shall, without leave of Court, use any material produced pursuant to this Ruling in connection with any formal or informal third-party discovery of individuals or entities revealed, including but not limited to: (i) requests to or about individuals whose records are produced; and (ii) requests to health care providers or administrators concerning the treatment of individuals described therein. In sum, no person shall contact or attempt to contact any individual identified in the medical records, or their family members or medical providers or other related staff, for the purpose of obtaining additional information related to this case, without leave of Court. Nothing in this order shall prohibit a party from conducting otherwise-allowed discovery from or relating to a person as to whom HIPAA-protected data has

been produced based on other information obtained, either in discovery or otherwise, concerning that person.

All protected health information produced pursuant to this Order shall be disclosed only to: (i) Outside Counsel for the parties in this action; (ii) in-house counsel for Defendants in this action with responsibility for overseeing this litigation; (iii) consulting and testifying experts retained specifically to provide services in this action; and (iv) court personnel and staff, including the Special Masters appointed in this action and their assistants. No other individuals shall be permitted to access protected health information, and all parties shall institute reasonable and appropriate steps to prevent against unauthorized disclosure.

5. **Breach Notification.** In the event that any Party learns of the unauthorized disclosure of protected health information subject to this Order, such Party shall provide prompt notification of the breach to counsel for each of the Track Two Plaintiffs, such notice to include: (1) the date of the breach; (2) the circumstances of the breach; (3) the identity or identities of the unauthorized recipients; and (4) all steps taken or planned to remedy the breach.

6. **Limitations on Use.** All protected health information produced pursuant to this Order has been produced solely for purposes of this litigation, and shall only be used for purposes of this litigation.

7. **Restrictions on Third-Party Discovery.** All prior restrictions on the use of protected health information in connection with third party discovery remain in effect, including the limitations on third party discovery set forth in Discovery Ruling No. 7, as clarified by the Special Master.

Entered this the 13th day of December, 2019.

/s/David R. Cohen  
Special Master



# Exhibit 2

## UNITED STATES DISTRICT COURT

for the

Southern District of West Virginia

City of Huntington; Cabell County Commission

*Plaintiff*

v.

AmerisourceBergen Drug Corporation, et al.

*Defendant*

Civil Action No. 3:17-01362; 3:17-01665

## SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: U.S. Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152

(Name of person to whom this subpoena is directed)

☒ **Testimony:** **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

See Schedule A

Place: Covington & Burling LLP  
850 10th Street NW  
Washington, DC 20001

Date and Time:

03/12/2020 9:00 am

The deposition will be recorded by this method: Stenograph and Videotape

☐ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: \_\_\_\_\_

CLERK OF COURT

OR

\_\_\_\_\_  
Signature of Clerk or Deputy Clerk\_\_\_\_\_  
Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing (name of party) All Defendants  
McKesson Corporation

, who issues or requests this subpoena, are:  
Jeff Wakefield, 200 Capitol Street, Charleston, WV 25301, jwakefield@flahertylegal.com, (304) 347-4231

## Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 3:17-01362; 3:17-01665

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)*

I received this subpoena for *(name of individual and title, if any)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_.

☐ I served the subpoena by delivering a copy to the named individual as follows: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I returned the subpoena unexecuted because: \_\_\_\_\_  
\_\_\_\_\_.

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also  
tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of  
\$ \_\_\_\_\_.

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_  
\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc.:

**Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)****(c) Place of Compliance.**

**(1) For a Trial, Hearing, or Deposition.** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
  - (i) is a party or a party's officer; or
  - (ii) is commanded to attend a trial and would not incur substantial expense.

**(2) For Other Discovery.** A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

**(d) Protecting a Person Subject to a Subpoena; Enforcement.**

**(1) Avoiding Undue Burden or Expense; Sanctions.** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

**(2) Command to Produce Materials or Permit Inspection.**

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

**(3) Quashing or Modifying a Subpoena.**

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

**(e) Duties in Responding to a Subpoena.**

**(1) Producing Documents or Electronically Stored Information.** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

**(2) Claiming Privilege or Protection.**

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

**(g) Contempt.**

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

### **Requests for Testimony from the Drug Enforcement Administration**

#### **DEFINITIONS**

The following terms shall have the meanings set forth below. Other terms shall have their plain meaning.

1. “You” and “Your” refers to the Drug Enforcement Administration (“DEA”) and all others acting or purporting to act on DEA’s behalf, including any employees, officers, committees, subcommittees, working groups, and joint task forces.
2. “Communication” means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
3. “Defendants” means all defendants named in *The City of Huntington v. AmerisourceBergen Drug Corporation*, 3:17-01362 (S.D. W. Va.), or *Cabell County Commission v. AmerisourceBergen Drug Corporation*, 3:17-01665 (S.D. W. Va.), as of the date of this notice.
4. “Prescription Opioids” means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in West Virginia only through prescriptions filled by dispensers duly licensed and regulated.
5. “Illicit Opioids” means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not obtained from a licensed practitioner pursuant to a legitimate prescription. Illicit opioids include but are not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, counterfeit opioid medications, and Prescription Opioids that are diverted.
6. “DEA Registrant” or “Registrant” means Registrant as defined in 21 C.F.R. § 1300.01(b) (“any person who is registered pursuant to either section 303 or section 1008 of the [Controlled Substances] Act”).
7. “Suspicious Order Report” means a report filed by DEA Registrants pursuant to 21 C.F.R. § 1301.74(b).
8. “ARCOS Data” means data reported by DEA Registrants pursuant to 21 U.S.C. § 827 through the Automation of Reports and Consolidated Orders System.
9. “Aggregate Production Quota” means the quantity of Prescription Opioids “necessary to be manufactured during the following calendar year to provide for the estimated medical,

scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks” per 21 C.F.R § 1303.11.

### **TOPICS FOR EXAMINATION**

The topics upon which the person or persons designated by You are asked to be prepared to testify in accordance with Rule 30(b)(6) are:

1. Determination of estimates of diversion for Prescription Opioids during the Relevant Time Period pursuant to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Pub. L. 115-271, 132 Stat. 3894. See [https://www.deadiversion.usdoj.gov/fed\\_regs/quotas/2019/fr0912.htm](https://www.deadiversion.usdoj.gov/fed_regs/quotas/2019/fr0912.htm).
2. Your efforts to combat the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County, including any arrests, investigations, or indictments for crimes
3. Recommendations for actions to be taken by You or any federal, state, or local agency within the City of Huntington, Cabell County, or any town, village, or city within Cabell County, to combat the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids.
4. The structure and operation of the DEA within West Virginia, including DEA’s decision to establish only one Tactical Diversion Squad in West Virginia until 2016.
5. Your Communications with any federal, state, or local agency (including but not limited to the West Virginia Board of Pharmacy, the West Virginia Board of Medicine, the West Virginia Board of Osteopathic Medicine, the West Virginia Board of Dentistry, the West Virginia State Board of Examiners for Licensed Practical Nurses, the West Virginia State Board of Examiners for Registered Professional Nurses, the Department of Justice, the FBI, other federal, state, and local law enforcement entities), and the City of Huntington, Cabell County, or any town, village, or city within Cabell County regarding Illicit Opioids, Prescription Opioids, diversion, or the opioid epidemic.
6. Your use of the Suspicious Order Reporting System (SORS), ARCOS data, or any other communications from Defendants to combat the diversion or misuse of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
7. Your use of suspicious order reports submitted by wholesale distributor registrants to DEA Headquarters relating to West Virginia registrants, including but not limited to the transmittal of such suspicious order reports to DEA Diversion Investigators responsible for West Virginia and/or other federal, state or local government agencies.
8. Any investigation of suspicious orders reported by wholesale distributor registrants for West Virginia pharmacies, hospitals, or other dispensers for the Relevant Time Period.



9. Your use of ARCOS data or West Virginia Controlled Substance Automated Prescription Program data to investigate West Virginia pharmacies, pharmacists, or health care providers for the Relevant Time Period.
10. Any proposed changes to 21 U.S.C. § 823, 21 C.F.R. § 1301.74, or any other DEA regulation and/or guidance with respect to suspicious orders for controlled substances, including but not limited to Your internal Communications and external Communications with registrants and the United States Congress.
11. Your investigation of Safescript Pharmacy #6 in the United States District Court for the Southern District of West Virginia, Huntington Division (3:12-mj-00010) (February 15, 2012).
12. Your investigation of and decision to not prosecute Wendell Kent Freeman.
13. Your Communications with any federal, state, or local agency in or with jurisdiction over the City of Huntington, Cabell County, or any township, village, or city within Cabell County, and/or any distributor or manufacturer, regarding access to Suspicious Order Reporting System (SORS) and/or the ARCOS database.
14. DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Huntington, Cabell County, or any township, village, or city within Cabell County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances.
15. The determination of Aggregate Production Quotas for Prescription Opioids during the Relevant Time Period.
16. Communications with or about the Healthcare Distribution Alliance (HDA) or Healthcare Distribution Management Association (HDMA).
17. Communications with or about the Government Accountability Office (GAO) relating to the following report: *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders*, GAO-20-118 (Washington, D.C.: January 2020), and Your efforts to comply with recommendations provided in that report, if any.

# Exhibit 2

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

## UNITED STATES DISTRICT COURT

for the

Southern District of West Virginia

City of Huntington; Cabell County Commission

*Plaintiff*

v.

AmerisourceBergen Drug Corporation, et al.

*Defendant*

Civil Action No. 3:17-01362; 3:17-01665

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS  
OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTIONTo: U.S. Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152  
c/o U.S. Attorney for Southern District of WV, U.S. Courthouse, Suite 4000, 300 Virginia Street, Charleston, WV

(Name of person to whom this subpoena is directed)

☒ **Production:** **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See Schedule A

Place: Covington & Burling LLP  
850 10th Street NW  
Washington, DC 20001

Date and Time:

03/31/2020 9:00 am

☐ **Inspection of Premises:** **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:

Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 03/11/2020

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

/s/Jeffrey M. Wakefield

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing (name of party) \_\_\_\_\_  
McKesson Corporation, who issues or requests this subpoena, are:

Jeff Wakefield, 200 Capitol Street, Charleston, WV 25301, jwakefield@flahertylegal.com, (304) 347-4231

**Notice to the person who issues or requests this subpoena**

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

**Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)****(c) Place of Compliance.**

**(1) For a Trial, Hearing, or Deposition.** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
  - (i) is a party or a party's officer; or
  - (ii) is commanded to attend a trial and would not incur substantial expense.

**(2) For Other Discovery.** A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

**(d) Protecting a Person Subject to a Subpoena; Enforcement.**

**(1) Avoiding Undue Burden or Expense; Sanctions.** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

**(2) Command to Produce Materials or Permit Inspection.**

**(A) Appearance Not Required.** A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

**(B) Objections.** A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

**(3) Quashing or Modifying a Subpoena.**

**(A) When Required.** On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

**(B) When Permitted.** To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

- (i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

**(C) Specifying Conditions as an Alternative.** In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

**(e) Duties in Responding to a Subpoena.**

**(1) Producing Documents or Electronically Stored Information.** These procedures apply to producing documents or electronically stored information:

**(A) Documents.** A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

**(B) Form for Producing Electronically Stored Information Not Specified.** If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

**(C) Electronically Stored Information Produced in Only One Form.** The person responding need not produce the same electronically stored information in more than one form.

**(D) Inaccessible Electronically Stored Information.** The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

**(2) Claiming Privilege or Protection.**

**(A) Information Withheld.** A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

**(B) Information Produced.** If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

**(g) Contempt.**

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.



## SCHEDULE A

### Requests for Production of Documents to the Drug Enforcement Administration

#### DEFINITIONS

Notwithstanding any definition set forth below, each word, term, or phrase used in these Requests is intended to have the broadest meaning permitted under the Federal Rules of Civil Procedure and the Local Civil Rules for the U.S. District Court for the Southern District of West Virginia.

1. “You” and “Your” refers to the Drug Enforcement Administration (“DEA”) and all others acting or purporting to act on DEA’s behalf, including any employees, officers, committees, subcommittees, working groups, and joint task forces.
2. “Communication” means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
3. “Defendants” means all defendants named in *The City of Huntington v. AmerisourceBergen Drug Corporation*, 3:17-01362 (S.D. W. Va.), or *Cabell County Commission v. AmerisourceBergen Drug Corporation*, 3:17-01665 (S.D. W. Va.), as of the date of this notice.
4. “Document” has the full meaning ascribed to it by Federal Rule of Civil Procedure 34(a), and means the complete original (or complete copy where the original is unavailable) and each non-identical copy (where different from the original because of notes made on the copy or otherwise) of any writing or record, including, but not limited to, all written, typewritten, handwritten, printed, or graphic matter of any kind or nature, however produced or reproduced, any form of collected data for use with electronic data processing equipment, and any mechanical or electronic visual or sound recordings or text messages in Your possession, custody, or control. “Documents” include, but are not limited to, books, papers, contracts, memoranda, invoices, correspondence, notes, studies, reports, manuals, photographs, drawings, charts, graphs, data compilations, other writings, microfilm, microfiche, audio recordings, video recordings, electronic mail, and any other information stored in electronic form, and each different version or copy of each Document, including, but not limited to, drafts.
5. “Prescription Opioids” means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in West Virginia only through prescriptions filled by dispensers duly licensed and regulated by DEA.

6. "Illicit Opioids" means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not obtained from a licensed practitioner pursuant to a legitimate prescription. Illicit opioids include but are not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, counterfeit opioid medications, and Prescription Opioids that are diverted.
7. "DEA Registrant" or "Registrant" means Registrant as defined in 21 C.F.R. § 1300.01(b) ("any person who is registered pursuant to either section 303 or section 1008 of the [Controlled Substances] Act").
8. "Registration" means Registration as defined in 21 C.F.R. § 1300.01(b) ("registration required and permitted by sections 303 or 1007 of the [Controlled Substances] Act").
9. "Aggregate Production Quota" means the quantity of Prescription Opioids "necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks" per 21 C.F.R. § 1303.11.
10. "Suspicious Order Monitoring Program" means a system intended to aid in compliance with 21 C.F.R. § 1301.74 as defined by DEA to be required by 21 C.F.R. § 1301.74.

### **INSTRUCTIONS**

Should You consider any of the Documents requested to be confidential such that they should not be generally disseminated to the public or released to the press, we ask that You designate them as such under the Protective Orders in the MDL (copies attached) and the parties will deal with them accordingly.

To the extent You determine that any of the requests below implicate any type of law enforcement or investigative privilege, please identify which requests you believe implicate that privilege and please construe such requests to exclude Documents relating to current or ongoing investigations.

All of the following requests are intended to encompass Documents maintained in electronic or paper form, and "correspondence" or "Communications" include emails, letters or other papers, and memos reflecting oral Communications.

As these Documents will be shared with a large number of counsel and parties, we ask that You produce copies of them in electronic or paper form. Please let the undersigned know if there are charges or fees for searching or copying and, if so, also advise whether You will provide an invoice for the cost after production or if prepayment is required.



Unless otherwise indicated, the Relevant Time Period applicable to these requests is 1996 to the present.<sup>1</sup>

### **DOCUMENTS TO BE PRODUCED**

1. All Documents submitted by You to the House Energy and Commerce Committee as part of its investigation that resulted in the report *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, December 19, 2018, including but not limited to all Documents produced to the Committee, all written statements provided to Committee, and all notes, presentations, handouts and communications relating to the multiple briefings from DEA Staff to Committee Staff referenced in the Report.
2. All Documents and Communications concerning the determination of estimates of diversion for Prescription Opioids during the Relevant Time Period pursuant to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Pub. L. 115-271, 132 Stat. 3894. *See* [https://www.deadiversion.usdoj.gov/fed\\_regs/quotas/2019/fr0912.htm](https://www.deadiversion.usdoj.gov/fed_regs/quotas/2019/fr0912.htm).
3. All Documents describing, relating to, or reflecting efforts made by You to access or utilize ARCOS Data, Suspicious Order Reports, and/or West Virginia Controlled Substance Automated Prescription Program data to combat the diversion or misuse of Prescription Opioids in the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
4. All Documents referring or relating to the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
5. All Documents and data referring, tracking, or relating to any arrests, investigations, and indictments for crimes relating to the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
6. All Documents discussing, referring, or relating to Your efforts to combat the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
7. All Documents and Communications identifying, discussing, or relating to the individuals or entities You suspect or know have unlawfully produced, transported, diverted, sold, and/or

---

<sup>1</sup> Should the Court issue a ruling establishing a different time period for discovery, Defendants will revise the Relevant Time period accordingly.

trafficked Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.

8. All Documents referring or relating to Your efforts to suspend, revoke, or seek the suspension or revocation of registrations or licenses of, or fine or otherwise sanction any distributors, doctors, pharmacies, pharmacists, healthcare providers or other persons or entities because of the alleged diversion or trafficking of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
9. All Documents that state, discuss, reflect, or suggest recommendations for actions to be taken by You or any federal, state, or local agency within the City of Huntington, Cabell County, or any town, village, or city within Cabell County, to combat the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids.
10. Documents sufficient to show the structure and operation of the DEA within West Virginia, including but not limited to organizational charts and all Documents discussing the operation of DEA within West Virginia and DEA's staffing in West Virginia.
11. All Documents referring or relating to any Defendant regarding the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
12. All Documents and Communications between You and any federal, state, or local agency (including but not limited to the West Virginia Board of Pharmacy, the West Virginia Board of Medicine, the West Virginia Board of Osteopathic Medicine, the West Virginia Board of Dentistry, the West Virginia State Board of Examiners for Licensed Practical Nurses, the West Virginia State Board of Examiners for Registered Professional Nurses, the Department of Justice, the FBI, other federal, state, and local law enforcement entities), and the City of Huntington, Cabell County, or any town, village, or city within Cabell County regarding Illicit Opioids, Prescription Opioids, diversion, or the opioid epidemic. Included within this response are all Documents and Communications regarding efforts to combat drug-related crime, respond to the opioid epidemic, or form a joint task force to combat the opioid epidemic.
13. All Documents reflecting or relating to any completed inspection, audit, or investigation conducted by You of any Defendant located in or distributing to pharmacies in West Virginia, including inspections, audits, and investigations that did not lead to any further investigation or enforcement action. Defendants can provide a list of registration numbers for the relevant distribution centers, if requested.
14. All Documents reflecting or relating to DEA's policies and procedures and training with respect to inspections, audits and/or investigations of registrations in West Virginia, and summary information of completed inspections, audits and/or investigations of licensees by year.

15. All Documents reflecting or relating to the DEA's policies, procedures, and training with respect to distribution or dispensing controlled substances for the treatment of pain.
16. All Communication between DEA Headquarters and DEA field offices related to Your use of the Suspicious Order Reporting System (SORS), ARCOS data, or any other communications from Defendants to combat the diversion or misuse of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
17. All Documents relating to Your use of suspicious order reports submitted by Defendants to DEA Headquarters relating to West Virginia registrants, including but not limited to the transmittal of such suspicious order reports to DEA Diversion Investigators responsible for West Virginia and/or other federal, state or local government agencies.
18. All Documents related to any investigation of suspicious orders reported by Defendants for West Virginia pharmacies, hospitals, or other dispensers for the Relevant Time Period.
19. All Documents relating to Your use of ARCOS data to investigate West Virginia pharmacies, pharmacists, or health care providers for the Relevant Time Period.
20. All Documents and Communications relating to any proposed changes to 21 U.S.C. § 823, 21 C.F.R. § 1301.74, or any other DEA regulation and/or guidance with respect to suspicious orders for controlled substances, including but not limited to Your internal Communications and external Communications with registrants and the United States Congress.
21. All Documents and Communications relating to any action You took in response to the U.S. Department of Justice Office of the Inspector General's report entitled *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids* (September 2019), including but not limited to internal communications relating to the recommendation that DEA "establish regulations, policies, and procedures that specifically define what constitutes a suspicious order, as well as what information should be included in a suspicious order report."
22. All Documents and Communications relating to DEA's decision to establish only one Tactical Diversion Squad for West Virginia until 2016.
23. All Documents arising out of the search and seizure warrant executed on Safescript Pharmacy #6 in the United States District Court for the Southern District of West Virginia, Huntington Division (3:12-mj-00010) (February 15, 2012).
24. All Documents relating to Your investigation of and decision to not prosecute Wendell Kent Freeman.
25. Documents sufficient to identify those individuals at DEA responsible for receiving, analyzing, and disseminating suspicious order reports submitted to DEA Headquarters relating to the distribution of Prescription Opioids to West Virginia pharmacies, hospitals, and other dispensers during the Relevant Time Period.



26. All Documents relating to suspicious order reports for West Virginia pharmacies, hospitals, and other dispensers that were submitted directly to DEA field offices in West Virginia during the Relevant Time Period, and all actions taken resulting from the same.
27. All DEA files and records relating to diversion or misuse of Prescription Opioids in West Virginia, including but not limited to correspondence or complaints related to potential or actual diversion or misuse of Prescription Opioids, documents and correspondence reflecting any actions undertaken by DEA relating to such complaints, and any other records relating to such complaints.
28. All Documents and Communications with any federal, state, or local agency in or with jurisdiction over the City of Huntington, Cabell County, or any township, village, or city within Cabell County, and/or any distributor or manufacturer, regarding access to Suspicious Order Reporting System (SORS) and/or the ARCOS database.
29. All Documents or Communications concerning the DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Huntington, Cabell County, or any township, village, or city within Cabell County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances.
30. All Documents and Communications concerning the determination of Aggregate Production Quotas for Prescription Opioids during the Relevant Time Period.
31. All Documents concerning Communications with or about the Healthcare Distribution Alliance (HDA) or Healthcare Distribution Management Association (HDMA).
32. All Documents concerning Communications with or about the Government Accountability Office (GAO) relating to the following report: *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders*, GAO-20-118 (Washington, D.C.: January 2020).
33. All Documents DEA has identified or determined were retained by Joseph Rannazzisi upon the conclusion of his employment with DEA, as well as all documents concerning DEA's investigation of whether documents were retained by Mr. Rannazzisi upon the conclusion of his employment with DEA.
34. The complete personnel file relating to the employment of Joseph Rannazzisi by the DEA.
35. All Documents provided by the DEA or by any current or former employee of the DEA to the Washington Post and/or to 60 Minutes, and all Documents concerning DEA's investigation relating to Documents provided to the Washington Post and/or 60 Minutes.
36. All Documents and Communications between DEA registrants and the Office of Diversion Control's Liaison and Policy Section relating to registrants' obligations under 21 C.F.R. § 1301.74.

IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

**This document relates to:**

***All Cases***

**Case No.: 1:17-md-2804-DAP**

**Honorable Dan Aaron Polster**

**CASE MANAGEMENT ORDER NO. 2: PROTECTIVE ORDER**

**I. Scope of Order**

1. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the Court to enter the following Stipulated Protective Order ("Protective Order" or "Order"). Unless otherwise noted, this Order is also subject to the Local Rules of this District and the Federal Rules of Civil Procedure on matters of procedure and calculation of time periods. Unless otherwise stated, all periods of time provided for in this Order are calculated as calendar days

2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, captioned as *In re: National Prescription Opiate Litigation* (MDL No. 2804), Case No. 1:17-CV-2804, which includes any related actions that have been or will be originally filed in this Court, transferred to this Court, or removed to this Court and assigned there ("the Litigation"). All materials produced or adduced in the course of

discovery, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any Party to this Litigation (the "Producing Party") to any other party or parties (the "Receiving Party"). This Protective Order is binding upon all the Parties to this Litigation, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.

3. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.

4. The entry of this Protective Order does not preclude any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).

5. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential.

## **II. Definitions**

7. Party. "Party" means any of the parties in this Litigation at the time this Protective Order is entered, including officers and directors of such parties. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Confidential Information and/or Highly Confidential



Information as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

8. Discovery Material. "Discovery Material" means any information, document, or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) ("Computerized Material") is produced by any Party in such form, the Producing Party may designate such matters as confidential by a designation of "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" on the media. Whenever any Party to whom Computerized Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL is produced reduces such material to hardcopy form, that Party shall mark the hardcopy form with the corresponding "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation.

9. Competitor. Competitor means any company or individual, other than the Designating Party, engaged in the design; development; manufacture; regulatory review process; dispensing; marketing; distribution; creation, prosecution, pursuit, or other development of an interest in protecting intellectual property; and/or licensing of any product or services involving opioids; provided, however, that this section shall not be construed as limiting the disclosure of Discovery Material to an Expert in this Litigation, so long as the notice required under Paragraph 38 is provided to the Designating Party prior to any such disclosure where required, and so long as no Discovery Material produced by one Defendant is shown to any current employee or consultant of a different Defendant,

except as provided in Paragraphs 33 or 34.

10. Confidential Information. “Confidential Information” is defined herein as information that the Producing Party in good faith believes would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) on the basis that it constitutes, reflects, discloses, or contains information protected from disclosure by statute or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Health Information, protected law enforcement materials (including investigative files, overdose records, narcane, coroner’s records, court records, and prosecution files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as “Confidential.”

11. Highly Confidential Information. “Highly Confidential Information” is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not enumerated in Paragraphs 32 and 33, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective

Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as “Highly Confidential.”

12. Manufacturer Defendant: Manufacturer Defendant means any Defendant in this litigation that manufactures any Opioid Product for sale or distribution in the United States.

13. Distributor Defendant: Distributor Defendant means any Defendant in this litigation that distributes any Opioid Product in the United States other than a product they manufacture or license for manufacture.

14. Retail Defendant: Retail Defendant means any Defendant in this litigation that sells or distributes any Opioid Product directly to consumers in the United States.

15. Receiving Party. “Receiving Party” means a Party to this Litigation, and all employees, agents, and directors (other than Counsel) of the Party that receives Discovery Material from a Producing Party.

16. Producing Party. “Producing Party” means a Party to this Litigation, and all directors, employees, and agents (other than Counsel) of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party, subject to paragraph 3.

17. Protected Material. “Protected Material” means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that is designated as “Confidential” or “Highly Confidential” in accordance with this Protective Order.

18. Outside Counsel. “Outside Counsel” means any law firm or attorney who

represents any Party for purposes of this litigation.

19. In-House Counsel. “In-House Counsel” means attorney employees of any Party.

20. Counsel. “Counsel,” without another qualifier, means Outside Counsel and In- House Counsel.

21. Independent Expert. “Independent Expert” means an expert and/or independent consultant formally retained, and/or employed to advise or to assist Counsel in the preparation and/or trial of this Litigation, and their staff who are not employed by a Party to whom it is reasonably necessary to disclose Confidential Information or Highly Confidential Information for the purpose of this Litigation.

22. This Litigation. “This Litigation” means all actions in MDL No. 2804, *In re: National Prescription Opiate Litigation* or hereafter subject to transfer to MDL No. 2804.

### **III. Designation and Redaction of Confidential Information**

23. For each document produced by the Producing Party that contains or constitutes Confidential Information or Highly Confidential Information pursuant to this Protective Order, each page shall be marked “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER”, or “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER” or comparable notices.

24. Specific discovery responses produced by the Producing Party shall, if appropriate, be designated as Confidential Information or Highly Confidential Information by marking the pages of the document that contain such information with the notation “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER”, or “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER” or comparable notices.

25. Information disclosed through testimony at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party's receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or Highly Confidential Information and the "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed.

26. In accordance with this Protective Order, only the persons identified under Paragraphs 33 and 34, below, along with the witness and the witness's counsel may be present if any questions regarding Confidential Information or Highly Confidential are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

27. A Party in this Litigation may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" any document, material, or other information produced by, or testimony given by, any other person or entity that the designating Party reasonably believes



qualifies as the designating Party's Confidential Information or Highly Confidential Information pursuant to this Protective Order. The Party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party shall treat such information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same rights as a Producing Party under this Protective Order with respect to such information.

28. This Protective Order shall not be construed to protect from production or to permit the "Confidential Information" or "Highly Confidential Information" designation of any document that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

29. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, a Producing Party may redact certain Confidential or Highly Information from produced documents, materials or other things. The basis for any such redaction shall be stated in the Redaction field of the metadata produced pursuant to the Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Producing Party may redact:



(i) Personal Identifying Information. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees' names and business contact information) and (b) individuals in clinical studies or adverse event reports whose identity is protected by law.

(ii) Privileged Information. Information protected from disclosure by the attorney-client privilege, work product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.

(iii) Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 78, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce such documents in litigation.

30. To the extent any document, materials, or other things produced contain segregated, non-responsive Confidential or Highly Confidential Information concerning a Producing Party's non-opioid products (or, in the case of Plaintiffs, concerning programs, services, or agencies not at issue in this litigation), the Producing Party may redact that segregated, non-responsive, Confidential or Highly Confidential information except (a) that if a Producing Party's non-opioid product is mentioned in direct comparison to the Producing Party's opioid product, then the name and information about that product may not be redacted or (b) if the redaction of the name and information about the Producing Party's non-opioid product(s) would render the information pertaining to Producing Party's opioid product meaningless or would remove the context of the information about

Producing Party's opioid product, the name and information about the other product may not be redacted. Nothing in this paragraph shall restrict Plaintiffs' right and ability to request information about such other products nor restrict Defendants' right to object to or otherwise seek protection from the Court concerning any such request.

31. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients who were reported as experiencing adverse events that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as CONFIDENTIAL INFORMATION. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Producing Party.

#### **IV. Access to Confidential and Highly Confidential Information**

32. General. The Receiving Party and counsel for the Receiving Party shall not disclose or permit the disclosure of any Confidential or Highly Confidential Information to any third person or entity except as set forth in Paragraphs 33 and 34.

33. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 33.I) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;
- b. Vendor agents retained by the parties or counsel for the parties, provided

that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

- c. Individual Parties;
- d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph shall be deemed to permit the showing of one defendant's Confidential Information to an officer, director, or employee of another defendant, except to the extent otherwise authorized by this Order;
- e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- h. Any individual(s) who authored, prepared, or previously reviewed or received the information;

- i. To the extent contemplated by Case Management Order One, dated April 11, 2018 (Dkt. No. 232), those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation.
- j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- k. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;
- l. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification

contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order.; or

m. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

34. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 34.j) and its contents shall not be disclosed to any person unless



that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel of any Plaintiff, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. Information designated as Highly Confidential by any Defendant may be disclosed to one In-House counsel of another Defendant, provided that the In-House counsel (i) has regular involvement in the Litigation, (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the individual completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In-House Counsel is reasonably necessary to the Litigation;
- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;;
- c. Individual Parties that have produced the designated information;
- d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- e. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;



- f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- g. Any individual(s) who authored, prepared or previously reviewed or received the information;
- h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;
- j. Counsel for claimants litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient

agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant; or

- k. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Highly Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Highly Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

35. With respect to documents produced to Plaintiffs, documents designated as "HIGHLY CONFIDENTIAL" will be treated in the same manner as documents designated "CONFIDENTIAL," except that Plaintiffs may not disclose Highly Confidential Information to In-House Counsel (or current employees) of any Competitor of the Producing Party, except as otherwise provided in this Order or any other Order in this Litigation.

36. In the event that In-House Counsel (or current employees) of any Competitor of the Producing Party is present at the deposition of an employee or former employee of the Producing Party, prior to a document designated as Highly Confidential being used in the examination, such In-House Counsel (current employees) of any Competitor of the Producing Party shall excuse himself or herself from the deposition room without delaying or disrupting the deposition.

#### **V. Confidentiality Acknowledgment**

37. Each person required under this Order to complete the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound, shall be provided with a copy of this Protective Order, which he or she shall read, and, upon reading this Protective Order, shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Unless otherwise provided in this Order, Counsel for each Party shall maintain the Acknowledgments without giving copies to the other side. The Parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Protective Order, there will be no attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Protective Order, such disclosure will be pursuant to separate court order. Persons who come into contact with Confidential Information or Highly Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements, but must comply with the terms of this Protective Order.

## **VI. Litigation Experts and Consultants.**

38. Formally Retained Independent Experts and Consultants. Subject to the provisions of this Protective Order, all Confidential Information or Highly Confidential Information may be disclosed to any formally retained independent expert or consultant who has agreed in writing pursuant to Paragraph 37 or on the record of a deposition to be bound by this Protective Order. The party retaining an independent expert or consultant shall use diligent efforts to determine if the independent expert or consultant is currently working with or for a Competitor of a Producing Party in connection with a Competitor's opioid product. Prior to the initial disclosure of any information designated as Confidential Information or Highly Confidential Information to an expert or consultant who is currently working with or for a Competitor of the Producing Party in connection with a Competitor's opioid product, the party wishing to make such a disclosure ("Notifying Party") shall provide to counsel for the Producing Party in writing, which may include by e-mail, a statement that such disclosure will be made, identifying the general subject matter category of the Discovery Material to be disclosed, providing the nature of the affiliation with the Competitor entity and name of the Competitor entity, and stating the general purpose of such disclosure; the specific name of the formally retained independent expert or consultant need not be provided. The Producing Party shall have seven (7) days from its receipt of the notice to deliver to the Notifying Party its good faith written objections (if any), which may include e-mail, to such disclosure to the expert or consultant.

39. Absent timely objection, the expert or consultant shall be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order. Upon and pending resolution of a timely objection, disclosure to the expert or

consultant shall not be made. If the Notifying Party desires to challenge to the Producing Party's written objection to the expert or consultant, the Notifying Party shall so inform the Producing Party in writing, within ten (10) days of receipt of the Producing Party's written objection, of its reasons for challenging the objection. The expert or consultant shall then be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order after seven (7) days from receipt of the Producing Party's timely challenge to the written objection to the expert or consultant, unless within that seven day period, the Producing Party seeks relief from the Court pursuant to the procedures for discovery disputes set forth in Section 9(o) of Case Management Order One, or the Parties stipulate to an agreement. Once a motion is filed, disclosure shall not occur until the issue is decided by the Court and, if the motion is denied, the appeal period from the Court order denying the motion has expired. In making such motion, it shall be the Producing Party's burden to demonstrate good cause for preventing such disclosure.

#### **VII. Protection and Use of Confidential and Highly Confidential Information**

40. Persons receiving or having knowledge of Confidential Information or Highly Confidential Information by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Confidential Information or Highly Confidential Information only as permitted by this Protective Order. Counsel shall take reasonable steps to assure the security of any Confidential Information or Highly Confidential Information and will limit access to such material to those persons authorized by this Protective Order.

41. Nothing herein shall restrict a person qualified to receive Confidential



Information and Highly Confidential Information pursuant to this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this Litigation and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order.

42. All persons qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order shall at all times keep all notes, abstractions, or other work product derived from or containing Confidential Information or Highly Confidential Information in a manner to protect it from disclosure not in accordance with this Protective Order, and shall be obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other thing, or portions thereof (and the information contained therein) are returned and surrendered pursuant to Paragraph 46. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.

43. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Protective Order to use Confidential Information or Highly Confidential Information and, in the course thereof, relying upon such information, provided that in rendering such advice, Counsel



shall not disclose any other Party's Confidential Information or Highly Confidential Information other than in a manner provided for in this Protective Order.

44. Nothing contained in this Protective Order shall prejudice in any way the rights of any Party to object to the relevancy, authenticity, or admissibility into evidence of any document or other information subject to this Protective Order, or otherwise constitute or operate as an admission by any Party that any particular document or other information is or is not relevant, authentic, or admissible into evidence at any deposition, at trial, or in a hearing

45. Nothing contained in this Protective Order shall preclude any Party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any Party or the Court.

46. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party.

47. If a Receiving Party learns of any unauthorized disclosure of Confidential Information or Highly Confidential Information, it shall immediately (a) inform the Producing Party in writing of all pertinent facts relating to such disclosure; (b) make its best effort to retrieve all copies of the Confidential Information or Highly Confidential Information; (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order; and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.

48. Unless otherwise agreed or ordered, this Protective Order shall remain in force after dismissal or entry of final judgment not subject to further appeal of this Litigation.

49. Within ninety (90) days after dismissal or entry of final judgment not subject to further appeal of this Litigation, or such other time as the Producing Party may agree in writing, the Receiving Party shall return all Confidential Information and Highly Confidential Information under this Protective Order unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the Parties agree to destruction to the extent practicable in lieu of return;<sup>1</sup> or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that Party elects to destroy the documents and certifies to the producing party that it has done so.

50. Notwithstanding the above requirements to return or destroy documents, Plaintiffs' outside counsel and Defendants' outside counsel may retain (1) any materials required to be retained by law or ethical rules, (2) one copy of their work file and work product, and (3) one complete set of all documents filed with the Court including those filed under seal, deposition and trial transcripts, and deposition and trial exhibits. Any retained Confidential or Highly Confidential Discovery Material shall continue to be protected under this Protective Order. An attorney may use his or her work product in subsequent litigation, provided that the attorney's use does not disclose or use Confidential Information or Highly Confidential Information.

---

<sup>1</sup> The parties may choose to agree that the Receiving Party shall destroy documents containing Confidential Information or Highly Confidential Information and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate and return e-mails (including attachments to e-mails) that may include Confidential Information or Highly Confidential Information, or Confidential Information or Highly Confidential Information contained in deposition transcripts or drafts or final expert reports.

### **VIII. Changes in Designation of Information**

51. If a Party through inadvertence produces any Confidential Information or Highly Confidential Information without labeling or marking or otherwise designating it as such in accordance with the provisions of this Protective Order, the Producing Party may give written notice to the Receiving Party that the document or thing produced is deemed "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" and should be treated as such in accordance with the provisions of this Protective Order, and provide replacement media, images, and any associated production information to conform the document to the appropriate designation and facilitate use of the revised designation in the production. The Receiving Party must treat such documents and things with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to receive such information shall not be deemed a violation of this Protective Order. Any Producing Party may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" or withdraw a "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation from any material that it has produced consistent with this Protective Order, provided, however, that such redesignation shall be effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying Counsel for each Party in writing of such redesignation and providing replacement images bearing the appropriate description, along with the replacement media, images, and associated production information referenced above. Upon receipt of any redesignation and replacement image that designates material as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL", the Receiving Party shall (i) treat such material in accordance with this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this

Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order. It is understood that the Receiving Party's good faith efforts to procure all copies may not result in the actual return of all copies of such materials.

52. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of the chosen designation. If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, it shall notify the Producing Party and the Receiving Party shall have seven (7) days from such notification to challenge the designation by commencing a discovery dispute under the procedures set forth in Section 9(o) of Case Management Order One. The ultimate burden of persuasion in any such challenge proceeding shall be on the Producing Party as if the Producing Party were seeking a Protective Order pursuant to Fed. R. Civ. P. 26(c) in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the even that a designation is changed by the Producing Party or by Court Order, the Producing Party shall provide replacement media,

images, and associated production information as provided above.

#### **IX. Inadvertent Production of Documents**

53. Non-Waiver of Privilege. The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure ("Privileged Information"). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of further showing under Federal Rule of Evidence 502(b) and shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the "Disclosing Party"). This Section shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d).

54. Notice of Production of Privileged Information. If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, and may demand that the Receiving Party return or destroy the Privileged Information. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.



55. Recall of Privileged Information. If the Designating Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party's system:

i. Locate each recalled document in the document review/production database and delete the record from the database;

ii. If there is a native file link to the recalled document, remove the native file from the network path;

iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents. Remove the line(s) corresponding to the document image(s) from the image load file;

iv. Apply the same process to any additional copies of the document or database, where possible;

v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as



described herein;

vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the receiving party shall discard the original production media; or (ii) allow the receiving party to retain the original production media, in which case the receiving party shall take steps to ensure that the recalled document will not be used; and

vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

56. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

57. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted ("Clawed-Back Information"), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information. Within 14 days after receiving the Disclosing Party's privilege log with respect to such Clawed-Back Information, a receiving party may notify the Disclosing Party in writing of an objection to a claim of privilege or work-product protection with respect to the Clawed-Back Information. Within 14 days of the receipt of such notification, the Disclosing Party

and the objecting party shall meet and confer in an effort to resolve any disagreement concerning the Disclosing Party's privilege or work-product claim with respect to such Clawed-Back Information. The parties may stipulate to extend the time periods set forth in this paragraph.

58. If, for any reason, the Disclosing Party and Receiving Party (or parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Court pursuant to the procedures set forth in Case Management Order One. The Disclosing Party bears the burden of establishing the privileged or protected nature of any Privileged Information.

59. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

60. In the event any prior order or agreement between the parties and/or between the parties and a non-party concerning the disclosure of privileged and/or work product protected materials conflicts with any of the provisions of this Order, the provisions of this Stipulated Order shall control.

61. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Disclosing Party that such materials have been produced.

#### **X. Filing and Use at Trial of Protected Material**

62. Only Confidential or Highly Confidential portions of relevant documents

are subject to sealing. To the extent that a brief, memorandum, or pleading references any document designated as Confidential or Highly Confidential, then the brief, memorandum or pleading shall refer the Court to the particular exhibit filed under seal without disclosing the contents of any confidential information. If, however, the confidential information must be intertwined within the text of the document, a party may timely move the Court for leave to file both a redacted version for the public docket and an unredacted version for sealing.

63. Absent a Court-granted exception based upon extraordinary circumstances, any and all filings made under seal shall be submitted electronically and shall be linked to this Stipulated Protective Order or other relevant authorizing order. If both redacted and unredacted versions are being submitted for filing, each version shall be clearly named so there is no confusion as to why there are two entries on the docket for the same filing.

64. If the Court has granted an exception to electronic filing, a sealed filing shall be placed in a sealed envelope marked "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER." The sealed envelope shall display the case name and number, a designation as to what the document is, the name of the party on whose behalf it is submitted, and the name of the attorney who has filed the sealed document. A copy of this Stipulated Protective Order, or other relevant authorizing order, shall be included in the sealed envelope.

65. A Party that intends to present Confidential Information or Highly Confidential Information at a hearing shall bring that issue to the Court's and Parties' attention without disclosing the Confidential Information or Highly Confidential Information. The Court may thereafter make such orders, including any stipulated orders, as are necessary to govern the use of Confidential Information or Highly Confidential Information

at the hearing. The use of any Confidential Information or Highly Confidential Information at trial shall be governed by a separate stipulation and/or court order.

**XI. Information or Highly Confidential Information Requested by Third Party;  
Procedure Following Request.**

66. If any person receiving Discovery Material covered by this Protective Order (the "Receiver") is served with a subpoena, a request for information, or any other form of legal process that purports to compel disclosure of any Confidential Information or Highly Confidential Information covered by this Protective Order ("Request"), the Receiver must so notify the Designating Party, in writing, immediately and in no event more than five (5) court days after receiving the Request. Such notification must include a copy of the Request.

67. The Receiver also must immediately inform the party who made the Request ("Requesting Party") in writing that some or all the requested material is the subject of this Protective Order. In addition, the Receiver must deliver a copy of this Protective Order promptly to the Requesting Party.

68. The purpose of imposing these duties is to alert the interested persons to the existence of this Protective Order and to afford the Designating Party in this case an opportunity to protect its Confidential Information or Highly Confidential Information. The Designating Party shall bear the burden and the expense of seeking protection of its Confidential Information or Highly Confidential Information, and nothing in these provisions should be construed as authorizing or encouraging the Receiver in this Litigation to disobey a lawful directive from another court. The obligations set forth in this paragraph remain in effect while the Receiver has in its possession, custody or control Confidential Information or Highly Confidential Information by the other Party in this Litigation.

69. Materials that have been designated as Confidential or Highly Confidential Discovery Material shall not be provided or disclosed to any third party in response to a request under any public records act, or any similar federal, state or municipal law (collectively, the "Public Disclosure Laws"), and are exempt from disclosure pursuant to this Protective Order. If a Party to this Litigation receives such a request, it shall (i) provide a copy of this Protective Order to the Requesting Party and inform it that the requested materials are exempt from disclosure and that the Party is barred by this Protective Order from disclosing them, and (ii) promptly inform the Designating Party that has produced the requested material that the request has been made, identifying the name of the Requesting Party and the particular materials sought. If the Designating Party seeks a protective order, the Receiving Party shall not disclose such material until the Court has ruled on the request for a protective order. The restrictions in this paragraph shall not apply to materials that (i) the Designating Party expressly consents in writing to disclosure; or (ii) this Court has determined by court order to have been improperly designated as Confidential or Highly Confidential Discovery Material. The provisions of this section shall apply to any entity in receipt of Confidential or Highly Confidential Discovery Material governed by this Protective Order. Nothing in this Protective Order shall be deemed to (1) foreclose any Party from arguing that Discovery Material is not a public record for purposes of the Public Disclosure Laws; (2) prevent any Party from claiming any applicable exemption to the Public Disclosure Laws; or (3) limit any arguments that a Party may make as to why Discovery Material is exempt from disclosure.



## **XII.HIPAA-Protected Information**

70. General. Discovery in this Litigation may involve production of “Protected Health Information” as that term is defined and set forth in 45 C.F.R. § 160.103, for which special protection from public disclosure and from any purpose other than prosecuting this Action is warranted

71. “Protected Health Information” shall encompass information within the scope and definition set forth in 45 C.F.R. § 160.103 that is provided to the Parties by a covered entity as defined by 45 C.F.R. § 160.103 (“Covered Entities”) or by a business associate of a Covered Entity as defined by 45 C.F.R. § 160.103 (“Business Associate”) in the course of the Litigation, as well as information covered by the privacy laws of any individual states, as applicable.

72. Any Party who produces Protected Health Information in this Litigation shall designate such discovery material “Confidential Protected Health Information” in accordance with the provisions of this Protective Order.

73. Unless otherwise agreed between counsel for the Parties, the designation of discovery material as “Confidential Protected Health Information” shall be made at the following times: (a) for documents or things at the time of the production of the documents or things; (b) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and other documents, at the time of the service or filing, whichever occurs first; (c) for testimony, at the time such testimony is given by a statement designating the testimony as “Confidential Protected Health Information” made on the record or within thirty (30) days after receipt of the transcript of the deposition. The designation of discovery material as “Confidential Protected Health



Information” shall be made in the following manner: (a) on documents, by placing the notation “Confidential Protected Health Information” or similar legend on each page of such document; (b) for tangible things, by placing the notation “Confidential Protected Health Information” on the object or container thereof or if impracticable, as otherwise agreed by the parties; (c) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and any other documents containing Protected Health Information, by placing the notation “Confidential Protected Health Information” both on the face of such document and on any particular designated pages of such document; and (d) for testimony, by orally designating such testimony as being “Confidential Protected Health Information” at the time the testimony is given or by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days after receipt of the certified transcript of the deposition.

74. Pursuant to 45 C.F.R. § 164.512(e)(1), all Covered Entities and their Business Associates (as defined in 45 C.F.R. § 160.103), or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to the Action to those persons and for such purposes as designated in herein. Further, all Parties that are entities subject to state privacy law requirements, or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to this Action to those persons and for such purposes as designated in herein. The Court has determined that disclosure of such Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more parties to the proceedings.

75. The Parties shall not use or disclose Protected Health Information for any purpose other than the Litigation, including any appeals. The Parties may, inter alia, disclose Protected Health Information to (a) counsel for the Parties and employees of counsel who have responsibility for the Litigation; (b) the Court and its personnel; (c) Court reporters; (d) experts and consultants; and (e) other entities or persons involved in the Litigation.

76. Within sixty days after dismissal or entry of final judgment not subject to further appeal, the Parties, their counsel, and any person or entity in possession of Protected Health Information received pursuant to this Order shall destroy or return to the Covered Entity or Business Associate such Protected Health Information.

77. Nothing in this Order authorizes the parties to obtain Protected Health Information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or any other lawful process.

**XIII. Information Subject to Existing Obligation of Confidentiality Independent of this Protective Order.**

78. In the event that a Party is required by a valid discovery request to produce any information held by it subject to an obligation of confidentiality in favor of a third party, the Party shall, promptly upon recognizing that such third party's rights are implicated, provide the third party with a copy of this Protective Order and (i) inform the third party in writing of the Party's obligation to produce such information in connection with this Litigation and of its intention to do so, subject to the protections of this Protective Order; (ii) inform the third party in writing of the third party's right within fourteen (14) days to seek further protection or other relief from the Court if, in good faith, it believes such information to be confidential under the said obligation and either objects to the Party's

production of such information or regards the provisions of this Protective Order to be inadequate; and (iii) seek the third party's consent to such disclosure if that third party does not plan to object. Thereafter, the Party shall refrain from producing such information for a period of fourteen (14) days in order to permit the third party an opportunity to seek relief from the Court, unless the third party earlier consents to disclosure. If the third party fails to seek such relief, the Party shall promptly produce the information in question subject to the protections of this Protective Order, or alternatively, shall promptly seek to be relieved of this obligation or for clarification of this obligation by the Court.

#### **XIV. Miscellaneous Provisions**

79. Nothing in this Order or any action or agreement of a party under this Order limits the Court's power to make any orders that may be appropriate with respect to the use and disclosure of any documents produced or use in discovery or at trial.

80. Nothing in this Protective Order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.

81. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the Producing Party may immediately apply to obtain injunctive relief against any person violating or threatening to violate any of the terms of this Protective Order, and in the event the Producing Party shall do so, the respondent person, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the Producing Party possesses an adequate remedy at law.

82. This Protective Order shall not be construed as waiving any right to assert a claim of privilege, relevance, or other grounds for not producing Discovery

Material called for, and access to such Discovery Material shall be only as provided for by separate agreement of the Parties or by the Court.

83. This Protective Order may be amended without leave of the Court by agreement of Outside Counsel for the Parties in the form of a written stipulation filed with the Court. The Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of this Litigation.

84. Notwithstanding any other provision in the Order, nothing in this Protective Order shall affect or modify Defendants' ability to review Plaintiffs' information and report such information to any applicable regulatory agencies.

85. This Order is entered based on the representations and agreements of the parties and for the purpose of facilitating discovery. Nothing herein shall be construed or presented as a judicial determination that any documents or information designated as Confidential or Highly Confidential by counsel or the parties is subject to protection under Rule 26(c) of the Federal Rules of Civil Procedure or otherwise until such time as the Court may rule on a specific document or issue.

**IT IS SO ORDERED.**

Dated: 5/15/18

/s/Dan Aaron Polster  
Honorable Dan Aaron Polster  
United States District Judge

IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

**This document relates to:**

***All Cases***

**Case No.: 1:17-md-2804-DAP**

**Honorable Dan Aaron Polster**

**EXHIBIT A TO CASE MANAGEMENT ORDER NO. \_\_\_\_\_**

**ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND BY PROTECTIVE ORDER**

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Protective Order (CMO No. \_\_) that was issued by the United States District Court for the Northern District of Ohio on \_\_\_\_\_, 2018 in *In re: National Prescription Opiate Litigation* (the "Protective Order").

I agree to comply with and to be bound by all the terms of the Protective Order, and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to the Protective Order to any person or entity except in strict compliance with the provisions of the Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the Northern District of Ohio for the purposes of enforcing terms of the Protective Order, even if such enforcement proceedings occur after termination of these proceedings.

Date: \_\_\_\_\_

City and State where sworn and signed: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Signature: \_\_\_\_\_



**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>IN RE NATIONAL PRESCRIPTION</b>	)	<b>CASE NO. 17-MD-2804</b>
<b>OPIATE LITIGATION</b>	)	
	)	<b>SPECIAL MASTER COHEN</b>
<b>This document relates to:</b>	)	
<i>All Cases</i>	)	
	)	<b>AMENDMENTS TO CMO NO. 2</b>
	)	<b>RE: CONFIDENTIALITY AND</b>
	)	<b><u>PROTECTIVE ORDER</u></b>

The parties have agreed to make certain amendments to various paragraphs contained in the Court's Case Management Order No. 2 (docket no. 441) which address confidentiality and Protective Order issues. The parties submitted other proposed amendments upon which they could not agree. The Special Master now adopts the parties' agreed-upon revisions and also resolves the parties' disagreements, and amends CMO-2 accordingly, as set out in the attached document.

**RESPECTFULLY SUBMITTED,**

/s/ David R. Cohen

**David R. Cohen  
Special Master**

**Dated:** September 29, 2019

AMENDMENTS TO CONFIDENTIALITY & PROTECTIVE ORDER PROVISIONS  
OF CMO NO. 2 (docket no. 441)

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential. Parties shall not be overly broad in designating materials as Confidential or Highly Confidential under this Protective Order. If a Party is repetitively, overly broad in designating materials as Confidential or Highly Confidential, that Party risks having large categories of such designations denied protection. The Court expects and will assume that the attorney submitting the designation has reviewed it and does so subject to Rule 11.

10. Confidential Information. “Confidential Information” is defined herein as information that the Producing Party in good faith believes would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) on the basis that it constitutes, reflects, discloses, or contains information protected from disclosure by statute, or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Information, protected law enforcement materials (including investigative files, overdoes records, Narcan records, coroner’s records, court records, and prosecution files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Producing Party shall do so only after review of the documents or information by an attorney who has, in good faith, determined that the material would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the material is not otherwise publicly available, and that the material is not “stale” or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and rulings of the Special Master and the Court. Nothing herein shall be construed to allow for global designations of all documents as “Confidential.”

11. Highly Confidential Information. “Highly Confidential Information” is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not enumerated in Paragraphs 32 and 33, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so only after review of the documents or information by an attorney who has, in good faith, determined that the material would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the Producing Party has made reasonable efforts to keep the material confidential, that the material is not otherwise publicly available, and that the material is not “stale” or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and rulings of the Special Master and the Court. Nothing herein shall be construed to allow for global designations of all documents as “Highly Confidential.”

25. Information disclosed through testimony at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party's receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "HIGHLY CONFIDENTIAL-SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or Highly Confidential Information and the "HIGHLY CONFIDENTIAL-SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed. Any Confidential or Highly Confidential designations of deposition testimony by a party shall occur only if an attorney for that party has, in good faith, determined that the material is entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the Producing Party has made reasonable efforts to keep the material confidential, that the material is not otherwise publicly available, and that the material is not "stale" or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and the rulings of the Special Master and the Court. The Designating Party shall make page and line designations of deposition testimony; global designation of deposition testimony as Confidential or Highly Confidential is not permitted.

26. In accordance with this Protective Order, only the persons identified under Paragraphs 33 and 34 below, along with the witness and the witness's counsel, may be present if any questions regarding Confidential Information or Highly Confidential Information are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

27. A Party in this Litigation may designate as "Confidential" or "Highly Confidential" any document, material, or other information produced by, or testimony given by, any other person or entity that the designating Party reasonably believes qualifies as the designating Party's Confidential Information or Highly Confidential Information pursuant to this Protective Order. Any such designation may only be made after an attorney for the Designating Party has, in good faith, determined that the material would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c), that the Producing Party has made reasonable efforts to keep the material confidential, that the material is not otherwise publicly available, and that the material is not "stale" or old to a point where it is not entitled to protection consistent with the provisions of this Protective Order and rulings of the Special Master and the Court. The Party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party shall treat such



information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same duties and rights as a Producing Party under this Protective Order with respect to such information.

28. This Protective Order shall not be construed to protect from production any document, or to permit the “Confidential Information” or “Highly Confidential Information” designation of any document, that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

29. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, a Producing Party may redact certain Confidential or Highly Confidential Information from produced documents, materials or other things. The basis for any such redaction shall be stated in the Redaction field of the document and/or in the metadata produced pursuant to the Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Producing Party may redact or de-identify:

(i) Personal Identifying Information. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees’ names and business contact information), (b) individuals in clinical studies or adverse event reports whose identity is protected by law, (c) undercover law enforcement personnel and confidential informants, and (d) patient identified information that is protected by 42 CFR 2.12 and associated regulations consistent with the Order Governing Production of Medical and Pharmacy Claims Data in Track One Cases [Dkt. 1421].

(ii) Privileged Information. Information protected from disclosure by the attorney-client privilege, work-product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.

(iii) Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 78, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce documents in litigation.

Plaintiffs may withhold or redact the following specific protected information: (a) records of ongoing criminal investigations, and (b) records or information provided to the party by DEA, FBI, or other state or federal law enforcement agency that such agency designates is of a sensitive nature. The fact of redacting or withholding does not create a presumption that the redaction or withholding is valid, and Receiving Parties can challenge redactions freely after providing

appropriate notice to the Producing Party and (if applicable) the agency asserting the privilege or confidentiality redaction.

33. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 33.L) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;
- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- c. Individual Parties;
- d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph shall be deemed to permit the showing of one defendant's Confidential Information to an officer, director, or employee of another defendant, except to the extent otherwise authorized by this Order;
- e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- h. Any individual(s) who authored, prepared, or previously reviewed or received the information;
- i. To the extent contemplated by Case Management Order One, dated April 11, 2018 (Dkt. No. 232), those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation.
- j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the

Designating Party may request a meet and confer and may seek a protective order from the Court.

- k. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgment because such counsel is bound by the terms of this Protective Order;
- l. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, distribution, or dispensing of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgments and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant; provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order; or
- m. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

34. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 34.j) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

- a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. Information designated as Highly Confidential by any Defendant may be disclosed to In-House Counsel of another Defendant, provided that the In-House Counsel (i) has regular involvement in the Litigation (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the individual completes the certification contained in Exhibit



A, Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential Information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In-House Counsel is reasonably necessary to the Litigation;

- b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- c. Individual Parties that have produced the designated information;
- d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;
- e. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;
- f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;
- g. Any individual(s) who authored, prepared, or previously reviewed or received the information;
- h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.
- i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgment because such counsel is bound by the terms of this Protective Order;
- j. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, distribution, or dispensing of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgments and will receive Confidential and Highly Confidential Information pursuant to this Order

and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order; or

- k. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

46. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party. To the extent that a Producing Party's Confidential or Highly Confidential Information becomes part of the public record in this proceeding, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public through the Court record, the specific testimony, document excerpts, or other evidence will become and remain public. However, a Receiving Party shall not unnecessarily attempt to insert materials designated as Confidential or Highly Confidential into the Court record solely for purposes of making them public. Once information is made public, it is not confidential even if continued to be marked as such by the Producing Party, and the Receiving Party may freely use such information. A Receiving Party does not need to challenge Confidential or Highly Confidential designations of specific testimony, documents, or other evidence excerpts that become part of the public record in this proceeding. A Receiving Party can also challenge a designation for other testimony or portions of the excerpted document or other evidence as set forth in paragraph 52 below.

52. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document or deposition are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing, of its reasons why the confidentiality designation was not proper and must: (a) give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of the chosen designation, and (b) offer to provide the Producing Party with multiple alternatives (dates and times) to meet and confer during the seven (7) day period following the date of the

Receiving Party's written challenge notification. Thereafter, if a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, it shall notify the Producing Party, and the Receiving Party shall have seven (7) days from such notification to challenge the designation with the Court or Special Master. These time periods may be modified in emergent circumstances, as agreed to by the Challenging and Designating Parties, or as ordered by the Special Master or the Court. The ultimate burden of persuasion in any such challenge proceeding shall be on the Producing Party as if the Producing Party were seeking a Protective Order pursuant to Fed. R. Civ. P. 26(c) in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the event that a designation is changed by the Producing Party or by Court Order, the Producing Party shall provide replacement media, images, and associated production information as provided above. The parties are hereby notified that Discovery Ruling No. 20 Regarding Confidentiality Designations (Doc. 1650), as well as the "ARCOS Ruling" by the Sixth Circuit Court of Appeals (docket no. 1710), provide relevant legal standards, principles, and examples which should be followed and/or used as guidance relative to disputes over materials designated as Confidential or Highly Confidential at the discovery stage of the litigation.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>IN RE NATIONAL PRESCRIPTION</b>	)	<b>CASE NO. 17-MD-2804</b>
<b>OPIATE LITIGATION</b>	)	
	)	<b>SPECIAL MASTER COHEN</b>
<b>This document relates to:</b>	)	
<b>All Cases</b>	)	
	)	<b>AMENDMENT TO CMO NO. 2</b>
	)	<b><u>RE: INADVERTENT PRODUCTION</u></b>

The parties have agreed to make certain amendments to “Section IX. Inadvertent Production of Documents,” contained in the Court’s Case Management Order No. 2 (docket no. 441). The Court approves these amendments, which are set out in the attached document.

**RESPECTFULLY SUBMITTED,**

/s/ David R. Cohen

**David R. Cohen**  
**Special Master**

**Dated:** September 29, 2019



REPLACING SECTION IX OF CMO NO. 2 (docket no. 441)

**IX. Inadvertent Production of Documents**

53. **Non-Waiver of Privilege.** The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure (“Privileged Information”). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of further showing under Federal Rule of Evidence 502(b) and, pursuant to Federal Rule of Evidence 502(d), shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the “Disclosing Party”). This Section shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(b) and 502(d).

54. **Notice of Production of Privileged Information.**

a. **Notice by Designating Party.** If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, shall identify the type of privilege claimed, and may demand that the Receiving Party return or destroy the Privileged Information.

b. **Notice by Receiving Party.** In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

55. **Recall of Privileged Information.** If the Designating Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party’s system:

- i. Locate each recalled document in the document review/production database and delete the record from the database;
- ii. If there is a native file link to the recalled document, remove the native file from the network path;

- iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents. Remove the line(s) corresponding to the document image(s) from the image load file;
- iv. Apply the same process to any additional copies of the document or database where possible;
- v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as described herein;
- vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the receiving party shall discard the original production media; or (ii) allow the receiving party to retain the original production media, in which case the receiving party shall take steps to ensure that the recalled document will not be used; and
- vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

56. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

57. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted ("Clawed-Back Information"), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information.

58. If, for any reason, the Designating Party and Receiving Party (or parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Special Master pursuant to the procedures set forth in Case Management Order One and established by the Special Master. The Designating Party bears the burden of establishing the privileged or protected nature of any Privileged Information. For circumstances where the Parties are unable to reach an agreement, the procedure for submission to the Special Master is as follows:

- i. Receiving Party shall file its Motion to Compel and request for *in camera* submission to the Special Master with carbon copy to include only counsel for Receiving Party and Designating Party;



- ii. Designating Party shall file its opposition on a schedule agreed to by the Designating and Receiving Parties or as set by the Special Master, with carbon copy to Receiving Party's counsel;
- iii. The Receiving Party shall file its reply (if any) on a schedule agreed to by the Designating and Receiving Parties or as set by the Special Master, with carbon copy to include only counsel for the Receiving Party and the Designating Party;
- iv. If necessary, a hearing shall be conducted just between the Designating Party, the Receiving Party, and the Special Master.

59. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

60. [REMOVED BY AGREEMENT OF THE PARTIES]

61. Nothing in this Order overrides an attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the other Party that such materials have been produced.

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION OPIATE  
LITIGATION**

This document relates to:

*“Track Two Cases”*

**MDL No. 2804**

**Case No. 17-md-2804**

**Special Master David Cohen**

**PROTECTIVE ORDER REGARDING DISCLOSURE  
BY PLAINTIFFS OF CONFIDENTIAL MEDICAL RECORDS**

WHEREAS, Distributor Defendants<sup>1</sup> served discovery upon the Track Two bellwether Plaintiffs which potentially requires the disclosure of protected health information governed by the Health Insurance Portability and Accountability Act of 1996 (hereinafter referred to as “HIPAA”); *R.K. v. St. Mary's Med. Ctr., Inc.*, 229 W. Va. 712, 735 S.E.2d 715 (2012); and

WHEREAS, this Court has addressed procedural safeguards to such disclosure throughout this litigation. *See e.g., Case Management Order No. 2: Protective Order* (Doc #: 441) (Doc #: 1357); *Track One Discovery Order Regarding Health-Related Information* (Doc #: 703); *Discovery Ruling No. 7* (Doc #: 1051); *November 21, 2018 Order* (Doc #: 1147); *Order Governing Production of Medical and Pharmacy Claims Data in Track One Cases* (Doc #: 1421); *Order Governing Production of Non-Party OptumRx, Inc.'s Pharmacy Claims Data for Track One Cases* (Doc #: 1635); *Order Governing Production Of Non-Party Humana Health Plan of Ohio, Inc.'s Medical And Pharmacy Claims Data For Track One Cases* (Doc #: 1641); *Amendment to CMO*

---

<sup>1</sup> The Distributor Defendants are AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation.

*No. 2 Re. Confidentiality and Protective Order (Doc # 2688); Amendment to CMO No. 2 Re: Inadvertent Production (Doc #: 2687); Agreed Order Governing Privilege (Doc #: 2882); and*

WHEREAS, the bellwether Plaintiffs desire to efficiently advance this litigation while preserving the privacy rights of the general public; and

WHEREAS, federal law provides this Court with the authority to compel the disclosure of protected health information while providing adequate safeguards; and

WHEREAS, the Plaintiffs and Distributor Defendants agree to the provisions below; now therefore

IT IS HEREBY ORDERED that the following provisions shall govern the production of protected health information in the Track Two Cases:

1. **Findings.** The Court hereby makes the following findings with respect to the production of protected health information:

- a. Good cause exists for the entry of this Order.
- b. Alternative methods of obtaining this information are not available or would not be effective.
- c. The public interest and the need for disclosure of this information, subject to the restrictions set forth herein, outweigh the potential injury to the patient, the physician-patient relationship, and the treatment services.
- d. The bellwether Plaintiffs shall produce relevant protected health information not implicated by Title 42, Part 2 of the Code of Federal Regulations ("Part 2"), without redaction.

e. Only those individuals who require the information for purposes of this litigation (as described below) may receive protected health information produced pursuant to this Order.

f. The procedures set forth herein are necessary to limit disclosure for the protection of the patient, the physician-patient relationship, and the treatment services.

3. **Designation.** Protected health information produced pursuant to this Order shall be produced with the following legend appearing in either the title of the electronic file or on the face of the document: "HIPAA PROTECTED HEALTH INFORMATION - ACCESS RESTRICTED TO ATTORNEYS AND EXPERTS."

4. **Restrictions on Disclosure.** All parties shall safeguard and maintain the confidentiality of this information pursuant to the terms of the HIPAA protective order (*see* docket no. 441, CMO-2 at 32-34), and shall limit disclosure to attorneys and experts for the parties, unless otherwise ordered by the Court. Specifically, no person shall, without leave of Court, use any material produced pursuant to this Ruling in connection with any formal or informal third-party discovery of individuals or entities revealed, including but not limited to: (i) requests to or about individuals whose records are produced; and (ii) requests to health care providers or administrators concerning the treatment of individuals described therein. In sum, no person shall contact or attempt to contact any individual identified in the medical records, or their family members or medical providers or other related staff, for the purpose of obtaining additional information related to this case, without leave of Court. Nothing in this order shall prohibit a party from conducting otherwise-allowed discovery from or relating to a person as to whom HIPAA-protected data has

been produced based on other information obtained, either in discovery or otherwise, concerning that person.

All protected health information produced pursuant to this Order shall be disclosed only to: (i) Outside Counsel for the parties in this action; (ii) in-house counsel for Defendants in this action with responsibility for overseeing this litigation; (iii) consulting and testifying experts retained specifically to provide services in this action; and (iv) court personnel and staff, including the Special Masters appointed in this action and their assistants. No other individuals shall be permitted to access protected health information, and all parties shall institute reasonable and appropriate steps to prevent against unauthorized disclosure.

5. **Breach Notification.** In the event that any Party learns of the unauthorized disclosure of protected health information subject to this Order, such Party shall provide prompt notification of the breach to counsel for each of the Track Two Plaintiffs, such notice to include: (1) the date of the breach; (2) the circumstances of the breach; (3) the identity or identities of the unauthorized recipients; and (4) all steps taken or planned to remedy the breach.

6. **Limitations on Use.** All protected health information produced pursuant to this Order has been produced solely for purposes of this litigation, and shall only be used for purposes of this litigation.



7. **Restrictions on Third-Party Discovery.** All prior restrictions on the use of protected health information in connection with third party discovery remain in effect, including the limitations on third party discovery set forth in Discovery Ruling No. 7, as clarified by the Special Master.

Entered this the 13th day of December, 2019.

/s/David R. Cohen  
Special Master

# Exhibit 3

AO 88A (Rev. 02/14) Subpoena to Testify at a Deposition in a Civil Action

## UNITED STATES DISTRICT COURT

for the

Southern District of West Virginia

City of Huntington; Cabell County Commission

Plaintiff

v.

AmerisourceBergen Drug Corporation, et al.

Defendant

Civil Action No. 3:17-01362; 3:17-01665

## SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: U.S. Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152  
 c/o U.S. Attorney for Southern District of WV, U.S. Courthouse, Suite 4000, 300 Virginia Street, Charleston, WV  
 (Name of person to whom this subpoena is directed)

☒ **Testimony:** **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:  
 See Schedule A

Place: Covington & Burling LLP 850 10th Street NW Washington, DC 20001	Date and Time: 03/31/2020 9:00 am
--	--------------------------------------

The deposition will be recorded by this method: Stenograph and Videotape

☐ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 03/11/2020

CLERK OF COURT

OR

/s/Jeffrey M. Wakefield

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing (name of party) Defendant  
McKesson Corporation, who issues or requests this subpoena, are:  
Jeff Wakefield, 200 Capitol Street, Charleston, WV 25301, jwakefield@flahertylegal.com, (304) 347-4231

**Notice to the person who issues or requests this subpoena**

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

**Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)****(c) Place of Compliance.**

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
  - (i) is a party or a party's officer; or
  - (ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

**(d) Protecting a Person Subject to a Subpoena; Enforcement.**

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

**(e) Duties in Responding to a Subpoena.**

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) *Contempt.*

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## SCHEDULE A

### Requests for Testimony from the Drug Enforcement Administration

#### DEFINITIONS

The following terms shall have the meanings set forth below. Other terms shall have their plain meaning.

1. “You” and “Your” refers to the Drug Enforcement Administration (“DEA”) and all others acting or purporting to act on DEA’s behalf, including any employees, officers, committees, subcommittees, working groups, and joint task forces.
2. “Communication” means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
3. “Defendants” means all defendants named in *The City of Huntington v. AmerisourceBergen Drug Corporation*, 3:17-01362 (S.D. W. Va.), or *Cabell County Commission v. AmerisourceBergen Drug Corporation*, 3:17-01665 (S.D. W. Va.), as of the date of this notice.
4. “Prescription Opioids” means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in West Virginia only through prescriptions filled by dispensers duly licensed and regulated.
5. “Illicit Opioids” means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not obtained from a licensed practitioner pursuant to a legitimate prescription. Illicit opioids include but are not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, counterfeit opioid medications, and Prescription Opioids that are diverted.
6. “DEA Registrant” or “Registrant” means Registrant as defined in 21 C.F.R. § 1300.01(b) (“any person who is registered pursuant to either section 303 or section 1008 of the [Controlled Substances] Act”).
7. “Suspicious Order Report” means a report filed by DEA Registrants pursuant to 21 C.F.R. § 1301.74(b).
8. “ARCOS Data” means data reported by DEA Registrants pursuant to 21 U.S.C. § 827 through the Automation of Reports and Consolidated Orders System.
9. “Aggregate Production Quota” means the quantity of Prescription Opioids “necessary to be manufactured during the following calendar year to provide for the estimated medical,



scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks” per 21 C.F.R § 1303.11.

### **TOPICS FOR EXAMINATION**

The topics upon which the person or persons designated by You are asked to be prepared to testify in accordance with Rule 30(b)(6) are:

1. Submissions by You to the House Energy and Commerce Committee as part of its investigation that resulted in the report *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, December 19, 2018, including but not limited to all Documents produced to the Committee, all written statements provided to Committee, and all notes, presentations, handouts and communications relating to the multiple briefings from DEA Staff to Committee Staff referenced in the Report.
2. Determination of estimates of diversion for Prescription Opioids during the Relevant Time Period pursuant to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Pub. L. 115-271, 132 Stat. 3894. *See* [https://www.deadiversion.usdoj.gov/fed\\_regs/quotas/2019/fr0912.htm](https://www.deadiversion.usdoj.gov/fed_regs/quotas/2019/fr0912.htm).
3. Efforts made by You to access or utilize ARCOS Data, Suspicious Order Reports, and/or West Virginia Controlled Substance Automated Prescription Program data to combat the diversion or misuse of Prescription Opioids in the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
4. The unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
5. Any arrests, investigations, and indictments for crimes relating to the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
6. Your efforts to combat the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
7. Individuals or entities You suspect or know have unlawfully produced, transported, diverted, sold, and/or trafficked Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
8. Your efforts to suspend, revoke, or seek the suspension or revocation of registrations or licenses of, or fine or otherwise sanction any distributors, doctors, pharmacies, pharmacists, healthcare providers or other persons or entities because of the alleged diversion or trafficking of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.

9. Recommendations for actions to be taken by You or any federal, state, or local agency within the City of Huntington, Cabell County, or any town, village, or city within Cabell County, to combat the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids.
10. The structure and operation of the DEA within West Virginia, including but not limited to organizational charts and all Documents discussing the operation of DEA within West Virginia and DEA's staffing in West Virginia.
11. Your Communications and Documents relating to any Defendant regarding the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
12. Your Communications with any federal, state, or local agency (including but not limited to the West Virginia Board of Pharmacy, the West Virginia Board of Medicine, the West Virginia Board of Osteopathic Medicine, the West Virginia Board of Dentistry, the West Virginia State Board of Examiners for Licensed Practical Nurses, the West Virginia State Board of Examiners for Registered Professional Nurses, the Department of Justice, the FBI, other federal, state, and local law enforcement entities), and the City of Huntington, Cabell County, or any town, village, or city within Cabell County regarding Illicit Opioids, Prescription Opioids, diversion, or the opioid epidemic. Included within this response are all Documents and Communications regarding efforts to combat drug-related crime, respond to the opioid epidemic, or form a joint task force to combat the opioid epidemic.
13. Your use of the Suspicious Order Reporting System (SORS), ARCOS data, or any other communications from Defendants to combat the diversion or misuse of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
14. Your use of suspicious order reports submitted by Defendants to DEA Headquarters relating to West Virginia registrants, including but not limited to the transmittal of such suspicious order reports to DEA Diversion Investigators responsible for West Virginia and/or other federal, state or local government agencies.
15. Any investigation of suspicious orders reported by Defendants for West Virginia pharmacies, hospitals, or other dispensers for the Relevant Time Period.
16. Your use of ARCOS data to investigate West Virginia pharmacies, pharmacists, or health care providers for the Relevant Time Period.
17. Any proposed changes to 21 U.S.C. § 823, 21 C.F.R. § 1301.74, or any other DEA regulation and/or guidance with respect to suspicious orders for controlled substances, including but not limited to Your internal Communications and external Communications with registrants and the United States Congress.
18. DEA's decision to establish only one Tactical Diversion Squad for West Virginia until 2016.

19. The search and seizure warrant executed on Safescript Pharmacy #6 in the United States District Court for the Southern District of West Virginia, Huntington Division (3:12-mj-00010) (February 15, 2012).
20. Your investigation of and decision to not prosecute Wendell Kent Freeman.
21. Individuals at DEA responsible for receiving, analyzing, and disseminating suspicious order reports submitted to DEA Headquarters relating to the distribution of Prescription Opioids to West Virginia pharmacies, hospitals, and other dispensers during the Relevant Time Period.
22. Suspicious order reports for West Virginia pharmacies, hospitals, and other dispensers that were submitted directly to DEA field offices in West Virginia during the Relevant Time Period, and all actions taken resulting from the same.
23. Diversion or misuse of Prescription Opioids in West Virginia, including but not limited to correspondence or complaints related to potential or actual diversion or misuse of Prescription Opioids, documents and correspondence reflecting any actions undertaken by DEA relating to such complaints, and any other records relating to such complaints.
24. Your Communications with any federal, state, or local agency in or with jurisdiction over the City of Huntington, Cabell County, or any township, village, or city within Cabell County, and/or any distributor or manufacturer, regarding access to Suspicious Order Reporting System (SORS) and/or the ARCOS database.
25. DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Huntington, Cabell County, or any township, village, or city within Cabell County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances.
26. The determination of Aggregate Production Quotas for Prescription Opioids during the Relevant Time Period.
27. Communications with or about the Healthcare Distribution Alliance (HDA) or Healthcare Distribution Management Association (HDMA).
28. Communications with or about the Government Accountability Office (GAO) relating to the following report: *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders*, GAO-20-118 (Washington, D.C.: January 2020).
29. Your identification of documents retained by Joseph Rannazzisi upon the conclusion of his employment with DEA, as well as all documents concerning DEA's investigation of whether documents were retained by Mr. Rannazzisi upon the conclusion of his employment with DEA.
30. Your identification of Documents provided by the DEA or by any current or former employee of the DEA to the Washington Post and/or to 60 Minutes, and all Documents concerning DEA's investigation relating to Documents provided to the Washington Post and/or 60 Minutes.

# Exhibit 4



**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION	)	MDL 2804
OPIATE LITIGATION	)	
	)	Case No. 1:17-md-2804
THIS DOCUMENT RELATES TO:	)	
	)	Judge Dan Aaron Polster
<i>Cabell County Comm’n v.</i>	)	
<i>AmerisourceBergen Drug Corp. et al.</i> , case	)	<b><u>RESPONSE TO MOTION FOR</u></b>
no. 3:17-CV-1665 (S.D.W.V.);	)	<b><u>CLARIFICATION</u></b>
	)	
<i>City of Huntington, W.V. v. Amerisource</i>	)	
<i>Bergen Drug Corp. et al</i> , case no. 3:17-cv-	)	
01362 (S.D.W.V.)	)	

The Court writes to address the Drug Enforcement Administration’s Motion to Clarify (Doc. #: 3260) (“*DEA Motion*”), which discusses two cases that were remanded from the MDL Court to the original transferor court in West Virginia: *Cabell County Commission v. AmerisourceBergen Drug Corp.*, case no. 3:17-CV-1665 (S.D.W.V.), and *City of Huntington, W.V. v. Amerisource Bergen Drug Corp.*, case no. 3:17-cv-1362 (S.D.W.V.).

In this multidistrict litigation, the Court and Special Master Cohen have overseen extensive global discovery, including discovery of third-parties such as the DEA. *See, e.g., Discovery Ruling No. 16 Regarding DEA Depositions*, Doc. #: 1386 (noting the parties and DEA had “negotiated over the scope of . . . requested discovery, and . . . come to partial agreement,” and the Special Master then resolved remaining disputes). As described accurately in the *DEA Motion*, the DEA and the parties thoroughly and vigorously negotiated the scope of MDL discovery, in light of the needs of the case and the burden on the DEA as a non-party, governmental agency. Disputes were



mediated and resolved by Special Master Cohen. Ultimately, DEA produced thousands of pages of documents and provided several witnesses for lengthy deposition.

After overseeing global discovery and assessing the overall status of the MDL, this Court suggested to the Judicial Panel on Multidistrict Litigation (“JPML”) that several cases be remanded as part of a strategic plan to facilitate efficient resolution of the MDL. The Court selected the West Virginia cases, in particular, because the status of case-specific and global discovery, pretrial rulings, and other litigation matters had advanced far enough to allow for fairly prompt trial in the transferor courts. *See Suggestion of Remand*, Doc. #: 2941 at 5–6 (telling the JPML that “the global discovery, pretrial rulings, and other litigation matters over which the undersigned has already presided provide a good base upon which the transferor courts can build”). In this Court’s view, the only remaining fact discovery the parties in the West Virginia cases would need after remand was limited to localized evidence pertaining to the specific jurisdiction.

According to DEA, the parties now seek additional discovery of the DEA in the West Virginia cases. DEA asserts the parties seek to reopen broad third-party fact discovery, with requests that are duplicative and far in excess of those previously negotiated and narrowed in the MDL. *See DEA Motion* at 3, exh. A (comparing requested MDL discovery of the DEA to requested West Virginia discovery of the DEA).

The Court writes in response to the *DEA Motion* only to clarify its view of the status of the West Virginia cases at the time of remand, in order to assist the transferor court. *See Manual for Complex Litigation (Fourth)* § 20.133 at 226 (at the time of remand, the transferee court should, among other things, “outline[] the issues remaining for discovery and trial”). As stated, this Court believed only limited, jurisdiction-specific discovery in the West Virginia cases would be necessary after remand. This Court did not believe additional discovery from the DEA was

necessary or appropriate for a fair trial, applying the standards set out in Rules 26, 30, and 45 of the Federal Rules of Civil Procedure.

That said, the undersigned is quick to add that discovery disputes in the West Virginia remanded cases are no longer within this Court's jurisdiction. Any further resolution of discovery disputes is within the purview of the transferor court. *See id.* 20.133 at 225 ("After remand, the transferor court has exclusive jurisdiction, and further proceedings in the transferee court with respect to a remanded case are not authorized absent a new transfer order by the Panel. \* \* \* Although the transferor judge has the power to vacate or modify rulings made by the transferee judge, subject to comity and 'law of the case' considerations, doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings.").

**/s/ Dan Aaron Polster April 17, 2020**  
**DAN AARON POLSTER**  
**UNITED STATES DISTRICT JUDGE**